# Pharmacy Purchasing Outlook

*Member-Publication of the National Pharmacy Purchasing Association (NPPA)*

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## Fun Las Vegas Events/Dining Info & August NPPA Conference

**By Amy Empson, NPPA Event & Office Assistant**

I cannot believe the NPPA 2024 Conference is soon upon us! I am as excited as I always am for the day to arrive. Our team starts to arrive the Friday and Saturday before the show starts, in order to get setup behind the scenes to make the magic happen. I always have first-day jitters though. For those of you that have met me, you may be surprised that even though I have what I call my Customer Service voice and attention, I had to take public speaking classes for three years to overcome extreme shyness. The first day I must get mentally ready to speak and to ensure that my part of our show goes off well.

This year, we have updated certain things a bit diffferently. First off, we changed the timing of the lectures. We broke up the day into two parts, which we truly hope helps the attendees with not having to sit for as long a time before relaxing for lunch with your fellow buyers and then heading over to the Exhibit Hall where you can walk around. The new schedule also helps to finish the days a bit earlier, so you may have dinners with other attendees or the vendors without having to be out as late the night before. We sincerely hope these changes help with the restlessness (and chill) that we have heard about from sitting in the lecture hall for so long.

Additionally we updated the layout of the Exhibit Hall vendor booths, to hopefully allow you to see each of the exhibitors more easily. We want you to be able to walk throughout the Exhibit Hall with a natural flow that allows you to talk to everyone without missing someone due to

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## NPPA's Outstanding Buyer Of The Year: First Nominations & More To Come

This edition of *Pharmacy Purchasing Outlook* includes the first nominations for our NPPA Outstanding Pharmacy Buyer of the Year Award Program, for year 2024.

Qualified NPPA-member nominees have the chance to win 1 of the following 3 distinctions and educational prize awards, as sponsored by NPPA (the National Pharmacy Purchasing Association).

| | |
|---|---|
| 1st Place: | $1,000 Award for Education/Travel |
| 2nd Place: | $500 Award for Education/Travel |
| 3rd Place: | $250 Award for Education/Travel |

Nominations by a third party as well as self-nominations are eligible, and multiple submissions are allowed for up to 3 per nominee (such as a self-nomination, a supervisor's comments and a coworker's comments).

Completed nominations will be printed here in NPPA's official member publication *PPO*, for all members to read. The top 3 awardees will be determined by a neutral panel of judges.

Awardees will then be honored at the 2024 NPPA Conference in August, and announced on our website as well as a later edition of *PPO* after the Conference.

Good luck to all nominees this year—you're all worthy in our eyes!

For those interested in nominating a buyer colleague or yourself in future, watch for our e-blast announcements to alert of the opening each year, usually in December or early January. Or check our website's home page or the Outstanding Buyer page under the Membership section, which also includes more information as well as photos of the previous year's awardees and a list of all the worthy nominees.

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### Highlights Inside This Edition

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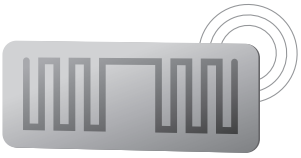

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# Join Us For The 27th Annual NPPA Conference In August 2024!

We hope you can all join us for our 27th Annual 2024 NPPA Conference, over August 19-22, 2024, at the Horseshoe Las Vegas hotel in Nevada.

**2024 NPPA: Tuesday, August 20 through Thursday, August 22**

**Opening Reception for Attendees: Monday, August 19**

**Attendee Registration** is now open! See the NPPA website (PharmacyPurchasing.com) for a link to register and contact our office for any questions you may have with the registration process or otherwise.

In addition, an optional **340B University event is also being offered** by the 340B Prime Vendor Program Managed By Apexus on Monday, August 19th, the day before our NPPA Conference begins, with no additional fee as sponsored by Apexus.

**Horseshoe hotel room rates** for the "2024 NPPA" Group Room Block are $65+tax per weeknight, with a ***discounted*** $35/night+tax Resort Fee.

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**NPPA Membership Rates:** $90, 1-year; $170, 2-years (comes with 6 editions/year of *Pharmacy Purchasing Outlook,* the member-publication of NPPA). Issues are distributed via First Class U.S. mail as well as in a digital PDF e-version. See details on our website.



# Within This Edition

# Editorial

**By Amy Empson**
**NPPA Event & Office Assistant**

**Dealing With Plantar Fasciitis (& Home Improvements!)**

Who can relate to the brutalness of home improvements? My partner and I are finally at the end of what feels like the end of the apocalypse. Our friends made jokes that we are still together. Who else can relate to the jokes we heard? Who can relate to the countless hours on what feels like the never-ending renovation?

Over a year ago, we sat down and made a list of the things we wanted to do in our home to update things. Each of us had things that were important to us. We visited stores, got ideas, and found a team to take on the project. Finally, this year, we began. Did I mention it was right before our 2023 NPPA Conference and Hurricane Hilary?

Sadly, I had little idea what we were walking into. Nor did I suspect we would add things to the project along the way. The first realization hit me when the dirt and dust inflamed my sinuses. I could not stay on top of the dust and dirt for months. It felt like a never-ending battle. I, unfortunately, do not thrive in chaos. Another thing I underestimated was my own ability to want to take on more when I should not. Between the two of us, we added more time for the renovations. They made sense and it was the perfect time to take them on. The problem during the kitchen renovation, I spent so much time on a stepstool and the floor, I cannot even begin to tell you what my body was screaming at me. I found myself in Urgent Care for a sore foot. I assumed it was just a strain as it was the lead foot during my climbing antics to reach areas to paint. However I was wrong. I learned a new painful phrase and condition–Plantar fasciitis.

I absolutely know the cause of how I developed it though, since I am one of those people who loves flip-flop sandals and wears them everywhere in the warmer months. I was wearing them on a stepladder as well, which was not exactly smart. They did not offer enough support and I was fully aware of that from having had a neuroma on the same foot 15 years ago. I could hear the doctor's lectures from that time explaining the importance of wearing shoes with good support in them. However I am tragically more comfortable in flip-flops than regular shoes. I was pushing a foot that was a bit more fragile after my previous surgery on it, so was 100% my own fault. I caused what is now an incredibly painful issue that I am treating full barrel.

I wanted to include the information on plantar fasciitis with the hopes you may find it helpful, and it will help prevent anyone from going this. The hours that hospital staff spend on their feet doing their countless duties is never ending. I want to try and help others not suffer from this painful condition.

The below details to follow is taken from the Mayo Clinic site about plantar fasciitis (www.mayoclinic.org/diseases-conditions/plantar-fasciitis/symptoms-causes/syc-20354846).

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**What is Planter's fasciitis?** Plantar fasciitis is one of the most common causes of heel pain. It involves inflammation of a thick band of tissue that runs across the bottom of each foot and connects the heel bone to the toes, known as the plantar fascia. Plantar fasciitis commonly causes stabbing pain that often occurs with your first steps in the morning. As you get up and move, the pain normally decreases, but it might return after extended periods of standing or when you stand up after sitting.

**Causes:** The plantar fascia is a band of tissue, called fascia, which connects your heel bone to the base of your toes. It supports the arch of the foot and absorbs shock when walking.

Tension and stress on the fascia can cause small tears. Repeated stretching and tearing of the facia can irritate or inflame it, although the cause remains unclear in many cases.

**Risk factors:** Even though plantar fasciitis can develop without an obvious cause, some factors can increase your risk of developing this condition. They include the following.

- **Age:** Plantar fasciitis is most common in people between the ages of 40 and 60.
- **Certain types of exercise:** Activities that place a lot of stress on your heel and attached tissue such as long-distance running, ballet dancing, and aerobic dance can contribute to its onset.
- **Foot mechanics:** Flat feet, a high arch or even an atypical pattern of walking can affect the way weight is distributed when you're standing and can put added stress on the plantar fascia.

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## *NPPA Mission*

The Mission of NPPA is to:

- Promote the Profession of Pharmacy Purchasing.
- Provide Specific and Enhanced Educational Opportunities for the Pharmacy Buyer.
- Provide a Unified Voice for the Professional Pharmacy Buyer.
- Affirm Pharmacy Purchasing as a unique and important specialty within the Pharmacy Profession.
- Affirm that Pharmacy Purchasing is an important aspect of Total Patient Care.

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# Generic Approvals & News

**Alvimopan Capsules Launch - Hikma Pharmaceuticals**

On February 13, Hikma Pharmaceuticals USA Inc. of Eatontown, New Jersey announced their ***launch*** of Alvimopan Capsules 12mg, having previously received FDA approval in late August 2023.

This product compares to Entereg® Capsules by Cubist Pharmaceuticals LLC (a subsidiary of Merck & Co., Inc.). It is indicated to accelerate the time of upper and lower gastrointestinal recovery following surgeries that include partial bowel resection.

Alvimopan Capsules had recent annual U.S. sales (ending November 2023) of $43 million, according to IQVIA.

**Aripiprazole Tablets - Lupin Pharmaceuticals**

On March 19, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they received final FDA approval for their Abbreviated New Drug Application (ANDA) to market Aripiprazole Tablets in the following strengths: 2mg, 5mg, 10mg, 15mg, 20mg, and 30mg.

This product compares to Abilify® Tablets in these strengths by Otsuka Pharmaceutical Company, Ltd., which had recent annual U.S. sales (ending January 2024) of $107 million, according to IQVIA. It is indicated for the treatment of schizophrenia, acute treatment of manic and mixed episodes associated with bipolar I disorder, adjunctive treatment of major depressive disorder, irritability associated with autistic disorder, and treatment of Tourette's disorder.

**Atorvastatin Calcium Tablets Launch - Camber Pharmaceuticals**

On March 1, Camber Pharmaceuticals, Inc. of Piscataway, New Jersey announced the ***launch*** of Atorvastatin Calcium Tablets.

- **10mg:** In 90-count bottles (NDC # 31722-424-90), 500-count bottles (NDC #31722-424-05), and 1,000-count bottles (NDC #31722-424-10).
- **20mg:** In 90-count bottles (NDC #31722-425-90), 500-count bottles (NDC #31722-425-05), and 1,000-count bottles (NDC #31722-425-10).
- **40mg:** In 90-count bottles (NDC #31722-426-90) and 500-count bottles (NDC #31722-426-05).
- **80mg:** In 90-count bottles (NDC #31722-427-90) and 500-count bottles (NDC #31722-427-05).

This product is AB-rated to Lipitor® Tablets by Viatris Inc. Atorvastatin Calcium Tablets are indicated together with diet, weight loss, and exercise to reduce the risk of heart attack and stroke and to decrease the chance that heart surgery will be needed in people who have heart disease or who are at risk of developing heart disease. It is also indicated to lower the amount of fatty substances such as low-density lipoprotein (LDL) cholesterol (bad cholesterol) and triglycerides in the blood and to increase the amount of high-density lipoprotein (HDL) cholesterol (good cholesterol) in the blood.

**Bivalirudin For Injection - Avenacy**

On January 29, Avenacy of Schaumburg, Illinois announced the FDA approval of Bivalirudin for Injection 250mg, and is available as a lyophilized powder in a single-dose vial for reconstitution.

This product is a therapeutic equivalent to Angiomax® for Injection by The Medicines Company. It is indicated for use as an anticoagulant treatment in patients undergoing percutaneous coronary intervention (PCI), including patients with heparin-induced thrombocytopenia and heparin-induced thrombocytopenia and thrombosis syndrome.

The package and label will also feature the company's highly differentiated packaging and labeling to support accurate medication selection and patient safety.

Recent annual U.S. sales (ending June 2023) of Bivalirudin for Injection were approximately $25 million.

Avenacy is a relatively new U.S.-based specialty pharmaceutical company, launched in early 2023, who are focused on supplying critical injectable medications used to treat patients in various medically supervised settings, from acute care hospitals to outpatient clinics and physician offices. They are supported by a global network of development and manufacturing partners, including Arthur Group as the Abbreviated New Drug Application (ANDA) holder and Qilu Pharmaceutical, Ltd. as the FDA-approved current Good Manufacturing Practice (CGMP) certified contract manufacturing organization.

**Ciprofloxacin/Dexamethasone Otic Suspension - Amneal Pharmaceuticals**

On March 25, Amneal Pharmaceuticals, Inc. of Bridgewater, New Jersey announced the final FDA approval of their Abbreviated New Drug Application (ANDA) for Ciprofloxacin/Dexamethasone Otic Suspension.

This product compares to Ciprodex® Otic Suspension by Alcon. It is a combination product of ciprofloxacin (a fluoroquinolone antibacterial) and dexamethasone (a corticosteroid) and is indicated for the treatment of infections caused by susceptible isolates of the designated microorganisms in acute otitis externa in pediatric (age 6 months and older), adult, and elderly patients due to *staphylococcus aureus* and *pseudomonas aeruginosa*.

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# Generic Approvals & News

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**Cyclophosphamide For Injection Launch - Fresenius Kabi**

On February 28, Fresenius Kabi USA, LLC of Lake Zurich, Illinois announced their ***launch*** of Cyclophosphamide for Injection in 500mg, 1Gm, and 2Gm single-dose vials of lyophilized powder, which can be administered intravenously or orally.

This product compares to Cytoxan® for Injection by Bristol Meyers Squibb Company *(now discontinued)*. It is indicated for use in treating several forms of cancer including: malignant lymphomas, Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma, multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of ovary, retinoblastoma, and breast carcinoma.

Fresenius Kabi offers all lyophilized presentations of Cyclophosphamide in the market.

**Diltiazem HCl SR Capsules - TWi Pharmaceuticals**

On March 2, TWi Pharmaceuticals USA, Inc. of Paramus, New Jersey announced they have received final FDA approval of their Abbreviated New Drug Application (ANDA) for Diltiazem Hydrochloride (HCl) Sustained Release (SR) Capsules.

Product is also now available.

Diltiazem HCl SR Capsules compares to Cardizem SR® Capsules by Bausch Health Companies Inc. *(now a discontinued product)*. It is indicated for the treatment of hypertension.

Recent annual U.S. sales (ending January 2023) were approximately $55.4 million, according to IQVIA.

**Doxycycline For Injection - Lupin Pharmaceuticals**

On March 15, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they received final FDA approval for their Abbreviated New Drug Application (ANDA) to market Doxycycline for Injection 100mg/vial in single-dose vials.

This product compares to Vibramycin® for Injection by Pfizer Inc. It is indicated to reduce development of drug-resistant bacteria and maintain the effectiveness of Doxycycline and other antibacterial drugs and should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Recent annual U.S. sales (ending January 2024) were $47 million, according to IQVIA.

**Enoxaparin Sodium Injection Launch - Sagent Pharmaceuticals**

On January 15, Sagent Pharmaceuticals, Inc. of Schaumburg, Illinois announced their ***launch*** of Enoxaparin Sodium Injection, available in single-dose syringes in 10-count cartons, as detailed below.

- **30mg/0.3mL:** Prefilled syringe (PFS) in 0.5mL container size (NDC #25021-410-70).
- **40mg/0.4mL:** PFS in 0.5mL container size (NDC #25021-410-76).
- **60mg/0.6mL:** Graduated PFS in 1mL container size (NDC #25021-410-77).
- **80mg/0.8 mL:** Graduated PFS in 1mL container size (NDC #25021-410-78).
- **100mg/1mL:** Graduated PFS in 1mL container size (NDC #25021-410-71).
- **120mg/0.8mL:** Graduated PFS in 1mL container size (NDC #25021-411-70).
- **150mg/1mL:** Graduated PFS in 1mL container size (NDC #25021-411-71).

This product is AP-rated to Lovenox® Injection by Sanofi-Aventis U.S. LLC. It is an anticoagulant drug that helps prevent the formation of blood clots. It is indicated to treat or prevent a type of blood clot called deep vein thrombosis (DVT), which can lead to blood clots in the lungs (pulmonary embolism) or can occur after certain types of surgery (or in people who are bed-ridden due to a prolonged illness). Additionally, it is also used to prevent blood vessel complications in people with certain types of angina or heart attack.

These products all come with Sagent's PreventIV Measures® features: easy-to-read drug name and dosage strength to aid in identifying the right product; barcodes included on the vial and carton for ease of scanning; unique label design to help products stand out on the shelf; and enhanced packaging and labeling designed to promote safety and help reduce the risk of medication errors.

**Febuxostat Tablets - Lupin Pharmaceuticals**

On January 18, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they received final FDA approval for their Abbreviated New Drug Application (ANDA) for Febuxostat Tablets in the strengths of 40mg and 80mg.

This product compares to Uloric® Tablets in these strengths by Takeda Pharmaceuticals U.S.A., Inc., which had recent annual U.S. sales (ending November 2023) of $27 million, according to IQVIA.

It is indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable.

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# Generic Approvals & News

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**Fentanyl Citrate Injection Prefilled Syringe (C-II) Launch - Hikma Pharmaceuticals**

On February 20, Hikma Pharmaceuticals USA Inc. of Eatontown, New Jersey announced their ***launch*** of Fentanyl Citrate Injection in 25mcg/0.5mL and 50mcg/mL doses.

This product compares to Sublimaze® Injection by Akorn, Inc. *(now a discontinued product)*.

Fentanyl Citrate (as an Injection or other presentations) has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 2 (C-II) controlled drug substance.

It is indicated for the following.

- Analgesic action of short duration during the anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period (recovery room) as the need arises.
- Use as a narcotic analgesic supplement in both general or regional anesthesia.
- Administration with a neuroleptic as an anesthetic premedication, for the induction of anesthesia and as an adjunct in the maintenance of general and regional anesthesia.
- Use as an anesthetic agent with oxygen in selected high-risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures.

**Fomepizole Injection Launch - Sagent Pharmaceuticals**

On January 15, Sagent Pharmaceuticals, Inc. of Schaumburg, Illinois announced their ***launch*** of Fomepizole Injection 1.5Gm/1.5mL (1Gm/mL) single-dose glass vials in 2mL container size (NDC #25021-829-02).

It is indicated to treat poisoning with ethylene glycol (antifreeze) or methanol (contained in solvents, fuels, and other household or automotive chemicals).

This product comes with Sagent's PreventIV Measures® features: easy-to-read drug name and dosage strength to aid in identifying the right product; barcodes included on the vial and carton for ease of scanning; unique label design to help products stand out on the shelf; and enhanced packaging and labeling designed to promote safety and help reduce the risk of medication errors.

**Gabapentin Tablets Launch - Camber Pharmaceuticals**

On March 5, Camber Pharmaceuticals, Inc. of Piscataway, New Jersey announced their ***launch*** of Gabapentin Tablets, available in 90-count bottles in the strengths of 300mg (NDC #31722-091-90) and 600mg (NDC #31722-092-90).

This product compares to Gralise® Once-Daily Tablets by Almatica Pharma LLC. It is indicated for the management of postherpetic neuralgia (PHN).

Camber already offers Gabapentin Tablets and Capsules (generic for Neurontin®). However, generics for Gralise and Neurontin are not interchangeable.

***Note:*** Bottle contains warning not to use Gabapentin Tablets interchangeably with other Gabapentin products.

**Gabapentin Tablets - Strides Pharma**

On March 5, Strides Pharma Inc. of Chestnut Ridge, New York announced they received final FDA approval for Gabapentin Tablets in the strengths of 600mg and 800mg.

This product compares to Neurontin® Tablets in these strengths by Viatris Specialty LLC. It is an anticonvulsant medication indicated to treat partial seizures and neuropathic pain (caused by diabetic neuropathy, postherpetic neuralgia, and central pain).

Gabapentin Tablets have a market size of $140 million, according to IQVIA.

**Ibuprofen/Famotidine Tablets Launch - Endo/Par Pharmaceuticals**

On March 26, Endo International plc of Dublin, Ireland (with U.S. headquarters in Malvern, Pennsylvania) and their wholly owned subsidiary, Par Pharmaceutical, Inc. of Woodcliff Lake, New Jersey announced the ***launch*** of Ibuprofen/Famotidine Tablets 800mg/26.6mg.

This product compares to Duexis® Tablets by Amgen Inc. (formerly Horizon Therapeutics USA, Inc.). It is a combination medication, indicated to relieve the signs and symptoms of rheumatoid arthritis and osteoarthritis while decreasing the risk of developing ulcers of the stomach and upper intestines people may experience from ibuprofen alone.

Ibuprofen/Famotidine Tablets had 2023 U.S. sales of $49 million, according to IQVIA.

**Isosapent Ethyl Capsules Launch - Camber**

On March 8, Camber Pharmaceuticals, Inc. of Piscataway, New Jersey announced their ***launch*** of Icosapent Ethyl Capsules as detailed below.

- **0.5Gm:** In 240-count bottles (NDC #31722-298-24).
- **1.0Gm:** In 120-count bottles (NDC#31722-299-12).

It is an ethyl ester of eicosapentaenoic acid (EPA) indicated as an adjunct to diet to reduce triglyceride (TG) levels in adults with severe (500mg/dL or greater) hypertriglyceridemia.

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# Generic Approvals & News

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**Ketorolac Tromethamine Ophthalmic Solution - Caplin Steriles**

On March 28, Caplin Steriles USA Inc. of Hamilton, New Jersey announced they received final FDA approval for their Abbreviated New Drug Application (ANDA) for Ketorolac Tromethamine Ophthalmic Solution 0.5% (eye drops).

This product compares to Acular® Ophthalmic Solution by Allergan, Inc., which had 2023 U.S. sales of $36 million, according to IQVIA. It is a nonsteroidal, anti-inflammatory drug indicated for the treatment of inflammation following cataract surgery and for temporary relief of ocular itching due to seasonal allergic conjunctivitis.

**Melphalan HCl For Injection - Avenacy**

On January 16, Avenacy of Schaumburg, Illinois announced the FDA approval of Melphalan Hydrochloride (HCl) for Injection.

This is a therapeutic equivalent to Alkeran® for Injection by Celgene Corporation. It is indicated for the palliative treatment of multiple myeloma patients for whom oral therapy is not appropriate.

Product is now available, and comes in a kit that contains a 50mg vial of lyophilized active ingredient and a 10mL vial of sterile diluent for admixture.

This product is formulated to allow storage at room temperature, enabling wider use in medical settings through greater transportability and ease of access. The package and label will also feature the company's highly differentiated packaging and labeling to support accurate medication selection and patient safety.

Recent annual U.S. sales (ending June 2023) of Melphalan HCl for Injection were approximately $25 million.

**Ofloxacin Otic Solution - Caplin Steriles**

On January 8, Caplin Steriles USA Inc. of Hamilton, New Jersey announced they received final FDA approval for their Abbreviated New Drug Application (ANDA) for Ofloxacin Otic Solution 0.3%.

This product compares to Floxin® Otic Solution by Daiichi Pharmaceuticals Inc. *(now a discontinued product)*. It is indicated as an anti-infective (antibacterial) for otic (ear) use.

Ofloxacin Otic Solution 0.3% had recent annual U.S. sales (ending June 2023) of $36 million, according to IQVIA.

**Orphenadrine Citrate Injection Launch - Sagent**

On January 7, Sagent Pharmaceuticals, Inc. of Schaumburg, Illinois announced their ***launch*** of Orphenadrine Citrate Injection 60mg/2mL (30mg/mL), available in single-dose glass vials in 10-count cartons (NDC #25021-651-02).

This product is AP-rated to Norflex® Injection by PAI Holdings, LLC. It is a muscle relaxant indicated, together with rest and physical therapy, to treat skeletal muscle conditions such as pain or injury.

This product comes with Sagent's PreventIV Measures® features: easy-to-read drug name and dosage strength to aid in identifying the right product; barcodes included on the vial and carton for ease of scanning; unique label design to help products stand out on the shelf; and enhanced packaging and labeling designed to promote safety and help reduce the risk of medication errors.

**Oxcarbazepine Oral Suspension Launch - Camber Pharmaceuticals**

On February 29, Camber Pharmaceuticals, Inc. of Piscataway, New Jersey announced their ***launch*** of Oxcarbazepine Oral Suspension 300mg/5mL, available in 250mL bottles.

This product compares to Trileptal® Oral Suspension by Novartis AG. It is indicated for the following.

- In adults: For monotherapy or adjunctive therapy, to treat partial onset seizures.
- In pediatrics: For monotherapy to treat partial onset seizures in children 4 to 16 years of age; and as adjunctive therapy in the treatment of partial onset seizures in children 2 to 16 years.

**Paliperidone Extended-Release Tablets Launch - Camber Pharmaceuticals**

On February 12, Camber Pharmaceuticals, Inc. of Piscataway, New Jersey announced their ***launch*** of Paliperidone Extended-Release Tablets, available in 30-count bottles in the following strengths: 1.5mg, 3mg, 6mg, and 9mg.

This product is AB-rated to Invega® Extended-Release Tablets by Janssen Pharmaceuticals, Inc. It is an atypical antipsychotic medication indicated for treatment of schizophrenia, treatment of schizoaffective disorder as monotherapy, and as an adjunct to mood stabilizers and/or antidepressants.

**Posaconazole Injection Launch - Fresenius Kabi**

On January 29, Fresenius Kabi USA, LLC of Lake Zurich, Illinois announced the ***launch*** of Posaconazole Injection 300mg/16.7mL vials.

This product compares to Noxafil® Injection by Merck & Co., Inc. It is used to treat invasive *aspergillosis,* a serious fungal infection, in adults and teenagers 13 years of age and older. It is also used to prevent invasive *aspergillus* and *candida* infections in patients who are severely immunocompromised, including adults and pediatric patients 2 years of age and older.

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# Generic Approvals & News

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Posaconazole Injection is produced at the company's pharmaceutical production site in Grand Island, New York. Fresenius Kabi has invested nearly $1 billion to expand and update its U.S. pharmaceutical production and distribution network. More than 70% of the product units shipped in the U.S. by Fresenius Kabi are drugs listed on the FDA's Essential Medicines List.

**Pregabalin Capsules (C-V) - Strides Pharma**

On January 25, Strides Pharma Inc. of Chestnut Ridge, New York announced they received final FDA approval for Pregabalin Capsules in the strengths of: 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, and 300mg.

This product compares to Lyrica® Capsules by Pfizer Inc.

Pregabalin has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 5 (C-V) controlled drug substance and is indicated for the treatment of fibromyalgia.

Recent annual market size of Pregabalin Capsules were estimated at $248 million, according to IQVIA.

**Propranolol HCl Extended-Release Capsules - Lupin**

On January 14, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they received final FDA approval for their Abbreviated New Drug Application (ANDA) for Propranolol HCl Extended-Release Capsules in strengths of 60mg, 80mg, 120mg, and 160mg.

This product compares to Inderal® LA Extended- Release Capsules in these same strengths.

It is indicated for the following.

- Management of hypertension either used alone or used with other antihypertensive agents, particularly a thiazide diuretic.
- To decrease angina frequency and increase exercise tolerance in patients with angina pectoris.
- For the prophylaxis of common migraine headache.
- To improve the New York Heart Association (NYHA) functional class symptoms in patients with hypertrophic subaortic stenosis.

Recent annual U.S. sales (ending November 2023) of Propranolol HCl Extended-Release Capsules were $71 million.

**Testosterone Topical Solution (C-III) Launch - TWi Pharmaceuticals**

On March 2, TWi Pharmaceuticals USA, Inc. of Paramus, New Jersey announced their ***launch*** of Testosterone Topical Solution.

This product compares to Axiron® Topical Solution by Eli Lilly & Company, which had recent annual U.S. sales (ending January 2023) of $9.8 million, according to IQVIA.

Testosterone has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 3 (C-III) controlled drug substance. It is indicated for hormone replacement in men who are not able to produce enough testosterone.

**Varenicline Tablets Launch - Lupin**

On January 10, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced their ***launch*** of Varenicline Tablets 0.5mg and 1mg, after receiving FDA approval.

This product compares to Chantix® Tablets in these strengths by PF Prism C.V., which had recent annual U.S. sales (ending November 2023) of $412 million, according to IQVIA. It is indicated for use as an aid to smoking cessation treatment.

## First Generic Versions

**Eslicarbazepine Acetate Tablets (Generic Aptiom®) - Lupin**

On March 28, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they received final FDA approval for their Abbreviated New Drug Application (ANDA) for Eslicarbazepine Acetate Tablets in the following strengths: 200mg, 400mg, 600mg, and 800mg.

This product compares to Aptiom® Tablets by Sumitomo Pharma America, Inc., which had recent annual U.S. sales of $354 million, according to IQVIA. It is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

Lupin is one of the first approved applicants for a Competitive Generic Therapy Designation (CGT) and is therefore eligible for 180 days of shared CGT exclusivity.

**Fluorometholone Ophthalmic Suspension (Generic FML®) Launch - Amneal**

On January 10, Amneal Pharmaceuticals, Inc. of Bridgewater, New Jersey announced their ***launch*** of Fluorometholone Ophthalmic Suspension, after its recent FDA approval.

This is the first generic version of FML® Suspension by Allergan, Inc. (an AbbVie company), which had recent annual U.S. sales (ending Nov. 2023) of $62 million. /

It is indicated to treat corticosteroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.

Amneal is the first approved applicant for a Competitive Generic Therapy Designation (CGT) and is therefore eligible for 180 days of CGT exclusivity.

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# Discontinued Drugs

### Ampicillin Sodium Injection By Sandoz

On March 4, the FDA announced that Sandoz Inc. of Princeton, New Jersey has discontinued the manufacture of Ampicillin Sodium Injection, in the following 10-count vial package presentations.

- **125mg:** Sandoz label (NDC #0781-3400-95) and Novaplus™ label (NDC #0781-9401-95).
- **250mg:** Novaplus label (NDC #0781-9402-95) and PREMIER Pro Rx® label (NDC #0781-9242-95).
- **500mg:** Novaplus label (NDC #0781-9407-95) and PREMIER Pro Rx label (NDC #0781-9250-95).

This product is a penicillin antibiotic indicated to treat or prevent different types of infections such as bladder infections, pneumonia, gonorrhea, meningitis, or infections of the stomach or intestines.

### Biltricide® Tablets

On March 5, the FDA announced that Bayer HealthCare Pharmaceuticals, Inc. of Whippany, New Jersey has discontinued the manufacture of Biltricide® (praziquantel) Tablets 600mg, in 60-count bottles (NDC #50419-747-01).

This product is indicated to treat infections caused by schistosoma worms, which enter the body through skin that has come into contact with contaminated water.

### Carbamazepine Extended-Release Capsules By Prasco Laboratories

On February 6, the FDA announced that Prasco Laboratories LLC of Mason, Ohio has discontinued the manufacture of Carbamazepine Capsules Extended-Release, in the following strengths (all in 120-count bottles).

- **100mg:** NDC #66993-407-32.
- **200mg:** NDC #66993-408-32.
- **300mg:** NDC #66993-409-32.

Note that the ***brand*** product by Takeda Pharmaceuticals USA Inc. ***will continue to be available:*** Carbatrol® XR (carbamazepine extended-release) Tablets in 120-count bottles.

Carbamazepine Extended Release is indicated to treat seizures.

### Carbidopa/Levodopa Tablets By Mylan Pharmaceuticals

On March 26, the FDA announced that Viatris Inc. of Canonsburg, Pennsylvania has discontinued the manufacture of Carbidopa/Levodopa Tablets (labeled as a Mylan Pharmaceuticals product, now a subsidiary of Viatris).

The discontinued strengths, all in 100-count bottles, are as follows.

- **10mg/100mg:** NDC #0378-0078-01.
- **25mg/100mg:** NDC #0378-0085-01.
- **25mg/250mg:** NDC #0378-1133-01.

Carbidopa and Levodopa tablets are a combination drug indicated in the treatment of Parkinson's disease, post-encephalitic parkinsonism, and symptomatic parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.

### Delflex® Peritoneal Dialysis Solution

On March 21, the FDA announced that Fresenius Medical Care North America of Waltham, Massachusetts has discontinued their manufacture of Delflex® Peritoneal Dialysis Solution, in the following 2,000mL concentrations.

- **1.5% Dextrose:** 18.4mg/100mL; 1.5Gm/100mL; 5.08mg/100mL; 538mg/100mL; 448mg/100mL (NDC #49230-206-20).
- **2.5% Dextrose:** 18.4mg/100mL; 2.5Gm/100mL; 5.08mg/100mL; 538mg/100mL; 448mg/100mL (NDC #49230-209-23).
- **4.5% Dextrose:** 18.4mg/100mL; 4.25Gm/100mL; 5.08mg/100mL; 538mg/100mL; 448mg/100mL (NDC #49230-212-23).

This product is indicated in the treatment of chronic kidney failure in patients being maintained on peritoneal dialysis.

### Diflucan® Tablets

On March 28, the FDA announced that Pfizer Inc. of New York City has discontinued the manufacture of Diflucan® (fluconazole) Tablets 200mg, in 100-count blister packs (NDC #0049-3430-41).

This product is indicated to treat infections caused by fungus, which can invade any part of the body including the mouth, throat, esophagus, lungs, bladder, genital area, and the blood.

### Extended Phenytoin Sodium Capsules 100mg By Amneal

On March 21, the FDA announced that Amneal Pharmaceuticals, LLC of Bridgewater, New Jersey has discontinued the manufacture of Extended Phenytoin Sodium Capsules 100mg, in the following presentations.

- **100-count bottles:** NDC #65162-212-10.
- **500-count bottles:** NDC #65162-212-50.
- **1,000-count bottles:** NDC #65162-212-11.

This product is indicated for the treatment of tonic-clonic (grand mal) and psychomotor (temporal lobe) seizures, and for the prevention and treatment of seizures occurring during or following neurosurgery.

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# Discontinued Drugs

*Continued from Page 12*

### E-Z-Paste® Esophageal Cream

On March 26, the FDA announced that Bracco Diagnostics, Inc. of Princeton, New Jersey has discontinued the manufacture of E-Z-Paste® (barium sulfate) Oral Esophageal Cream, in 454Gm tubes (NDC #32909-770-01).

This product is indicated in single contrast radiography of the esophagus, pharynx, hypopharynx, and for cardiac series.

### Folotyn® Injection

On March 21, the FDA announced that Fresenius Kabi USA, LLC of Lake Zurich, Illinois has discontinued the manufacture of Folotyn® (pralatrexate) Injection, in the following presentations.

- **20mg/mL:** single-dose vials (NDC #65219-550-01).
- **40mg/2mL (20mg/mL):** single-dose vials (NDC #65219-552-02).

This product is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).

### Furosemide Injection By Sagent Pharmaceuticals

On March 6, the FDA announced that Sagent Pharmaceuticals, Inc. of Schaumburg, Illinois has discontinued the manufacture of Furosemide Injection 10mg/mL, in single-dose vials as below.

- **20mg/2mL:** NDC #70860-302-41.
- **40mg/4mL:** NDC #70860-302-42.
- **100mg/10mL:** NDC #70860-302-43.

***Note:*** These products have an Athenex Pharmaceutical label.

Furosemide is a diuretic indicated to treat fluid retention (edema) in people with congestive heart failure, liver disease, or a kidney disorder such as nephrotic syndrome. This product is also used to treat high blood pressure (hypertension).

### Gentamicin Sulfate Injection By Hospira/Pfizer

On February 13, the FDA announced that Pfizer Inc. of New York City has discontinued the manufacture of Gentamicin Sulfate Injection 40mg/mL (labeled as a Hospira product), in 1-count single-dose vials (NDC #0409-1207-25).

Gentamicin sulfate injection is indicated in the treatment of serious infections caused by susceptible strains of the following microorganisms: *Pseudomonas aeruginosa*, *Proteus* species (indole-positive and indole-negative), *Escherichia coli*, *Klebsiella-Enterobacter-Serratia* species, *Citrobacter* species, and *Staphylococcus* species (coagulase-positive and coagulase-negative).

### Humalog® & Injection U-100 3mL Vials

On March 27, the FDA announced that Eli Lilly & Company of Indianapolis, Indiana has discontinued the manufacture of two presentations of their Humalog® (insulin lispro) product in 3mL multiple-dose vials, as follows.

1) Humalog Injection (NDC #0002-7533-01).
2) Humalog (insulin lispro, rDNA origin) 100 Units/mL (NDC #0002-7510-17).

***Note:*** The 10mL vial of Humalog is currently and will continue to be available, as well as the KwikPen® presentations of Humalog and Insulin Lispro Injection.

This product is indicated for the improvement of glycemic control in both adult and pediatric patients with diabetes mellitus.

### Humulin® R Regular & Injection, U-100 3mL Vials

On March 1, the FDA announced that Eli Lilly & Company of Indianapolis, Indiana has discontinued the manufacture of two presentations of their Humulin® R Regular product, as follows.

1) Humulin R Regular (insulin human) Injection 100 Units/mL in 3mL multi-dose vials (NDC #0002-0213-01).
2) Humulin R Regular (insulin human, rDNA origin) Injection 100 Units/mL in 3mL multi-dose vials (NDC #0002-8215-17).

***Note:*** The 10mL multi-dose vials for both above listed products is currently and will continue to be available.

Humulin R is indicated to improve glycemic control in patients with diabetes mellitus.

### Labetalol HCl Tablets By Teva Pharmaceuticals

On March 11, the FDA announced that Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey has discontinued the manufacture of Labetalol Hydrochloride (HCl) Tablets, in the following strengths.

- **100mg:** In 100-count bottles (NDC #0591-0605-01) and 500-count bottles (NDC #0591-0605-05).
- **200mg:** In 100-count bottles (NDC #0591-0606-01) and 500-count bottles (NDC #0591-0606-05).
- **300mg:** In 100-count bottles (NDC #0591-0607-01).

This product has the Activas Pharma, Inc. label, now an indirect wholly owned subsidiary of Teva Pharmaceuticals.

Labetalol is indicated in the management of hypertension. It also may be used alone or in combination with other antihypertensive agents, especially thiazide and loop diuretics.

*Continued on Page 14*

# Discontinued Drugs

*Continued from Page 13*

**Lanthanum Carbonate Chewable Tablets By Prasco Laboratories**

On February 6, the FDA announced that Prasco Laboratories LLC of Mason, Ohio has discontinued the manufacture of Lanthanum Carbonate Chewable Tablets, in the following strengths.

- **500mg:** In 2 bottles of 45-count tablets per patient pack (NDC #66993-422-85).
- **750mg:** In 6 bottles of 15-count tablets per patient pack (NDC #66993-423-85).
- **1,000mg:** In 9 bottles of 10-count tablets per patient pack (NDC #66993-424-85).

***Note:*** The name brand of this product—Fosrenol® (lanthanum carbonate) Tablets in the same strengths and quantities as above, is currently and will continue to be available (from Takeda Pharmaceuticals USA).

Lanthanum Carbonate is a phosphate binder indicated to reduce serum phosphate in patients with end-stage renal disease.

**Melphalan Tablets By Alvogen**

On February 23, the FDA announced that due to low sales volume, Alvogen, Inc. of Morristown, New Jersey has discontinued the manufacture of Melphalan Film-Coated Tablets 2mg, in 50-count bottles (NDC #47781-200-50).

This product is indicated for the palliative treatment of multiple myeloma and for the palliation of non-resectable epithelial carcinoma of the ovary.

**Mesalamine Delayed-Release Tablets By Takeda Pharmaceuticals**

On February 6, the FDA announced that Takeda Pharmaceutical USA, Inc. of Cambridge, Massachusetts has discontinued the manufacture of Mesalamine Delayed-Release Tablets 1.2Gm, in 120-count bottles (NDC #54092-100-01).

This product should be stored under refrigeration.

***Note:*** Takeda's brand product that compares—Lialda® (mesalamine) Delayed-Release Tablets 1.2Gm in 120-count boxes, is currently and will continue to be available.

Mesalamine Tablets Delayed-Release are indicated for the induction and maintenance of remission in adult patients with mild to moderately active ulcerative colitis.

**Methotrexate Injection By Accord Healthcare**

On February 5, the FDA announced that Accord Healthcare Inc. of Durham, North Carolina has discontinued the manufacture of Methotrexate Injection 25mg/10mL (25mg/mL), in 1-count single-dose vials (NDC #16729-277-03).

This product is indicated to treat rheumatoid arthritis, severe psoriasis, pediatric patients with polyarticular juvenile idiopathic arthritis (pJIA), as well as numerous types of neoplastic diseases.

**Methyldopa Tablets By Accord Healthcare**

On February 5, the FDA announced that Accord Healthcare Inc. of Durham, North Carolina has discontinued Methyldopa Film Coated Tablets, in the following strengths.

- **250mg:** In 100-count bottles (NDC #16729-030-01) and 500-count bottles (NDC #16729-030-16).
- **500mg:** In 100-count bottles (NDC #16729-031-01) and 500-count bottles (NDC #16729-031-16).

This product is indicated to treat hypertension (high blood pressure).

**Morphine Sulfate Extended Release (C-II) Tablets By Teva**

On March 5 the FDA announced that Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey has discontinued their manufacture of Morphine Sulfate Extended-Release Tablets, in the following strengths (all in 100-count bottles).

- **15mg:** NDC #0228-4270-11.
- **30mg:** NDC #0228-4271-11.
- **60mg:** NDC #0228-4311-11.
- **100mg:** NDC #0228-4323-11.
- **200mg:** NDC #0228-4347-11.

This product has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 2 (C-II) controlled drug substance.

Morphine Sulfate Extended Release is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, and for which alternative treatment options are inadequate.

**Nutropin AQ® NuSpin® Injection**

On March 22, the FDA announced that Genentech, Inc. of South San Francisco, California is discontinuing the manufacture of Nutropin AQ® NuSpin® (somatropin) Injection in the strengths listed below, which are all in 1-count boxes.

- **5mg/2mL:** (NDC #50242-075-01).
- **10mg/2mL:** (NDC #50242-074-01).
- **20mg/2mL:** (NDC #50242-076-01).

The discontinuation was a business decision made in light of the availability of generic and alternative treatments in the market.

*Continued on Page 16*

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# Discontinued Drugs

*Continued from Page 14*

This product is a man-made version of the human growth hormone that is indicated in adults or children who have certain conditions that prevent normal growth. These conditions include growth hormone deficiency (inability to produce enough growth hormone), chronic kidney disease, idiopathic short stature (unexplained shortness), Noonan syndrome, Turner syndrome, Prader-Willi syndrome (PWS), short stature homeobox-containing gene (SHOX) deficiency, and short stature born small for gestational age (SGA) with no catch-up growth by age 2 to 4 years of age.

***Note:*** This product is stored under refrigeration.

### Oxaliplatin Injection By Teva

On March 25, the FDA announced that Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey has discontinued Oxaliplatin Injection 5mg/mL single-dose vials, in the following strengths.

- **50mg:** NDC #45963-611-53.
- **100mg:** NDC #45963-611-59.

Oxaliplatin Injection is a cytotoxic chemotherapy medication indicated to treat cancer.

### Phenytoin Oral Suspension By VistaPharm

On February 28, the FDA announced that VistaPharm, Inc. of Largo, Florida has discontinued the manufacture of Phenytoin Oral Suspension 125mg/5mL, in the following presentations.

- **Bottles:** 8-fluid ounces (237mL), NDC #66689-775-08.
- **Cases:** 50-count 4mL unit-dose cups per case packaged in 5 trays of 10 each (NDC #66689-036-50).

This product is indicated for the treatment of tonic-clonic (grand mal) and psychomotor (temporal lobe) seizures.

### Potassium Chloride Injection By B. Braun

On February 2, the FDA announced that B. Braun Medical, Inc. of Irvine, California has discontinued the manufacture of Potassium Chloride Injection 14.9Gm/100mL, in 250mL bottles (NDC #0264-1940-20).

This product is indicated for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient.

### Triazolam Tablets (C-IV) By Hikma Pharmaceuticals

On January 22, the FDA announced that Hikma Pharmaceuticals USA, Inc. of Eatontown, New Jersey has discontinued the manufacture of Triazolam Tablets, in the following strengths.

- **0.125mg:** In 100-count bottles (NDC #0054-4858-25).
- **0.25mg:** In 100-count bottles (NDC #0054-4859-25) and 500-count bottles (NDC #0054-4859-29).

Triazolam has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 4 (C-IV) controlled drug substance. It is indicated for the short-term treatment of insomnia (generally 7 to 10 days) in adults.

### Vaprisol® Conivaptan HCl Injection

On January 22, the FDA announced that Cumberland Pharmaceuticals, Inc. of Nashville, Tennessee has discontinued the manufacture of Vaprisol® (conivaptan HCl) Premixed in 5% Dextrose in Plastic Container Injection, as follows.

- 20mg/100mL (0.2mg/mL), in 1-count single-dose INTRAVIA container per box (NDC #66220-160-10).

This product is indicated to treat hyponatremia (low sodium levels).

### Valproate Sodium Injection By Sagent/ Athenex Label

On January 9, the FDA announced that Sagent Pharmaceuticals, Inc. of Schaumburg, Illinois has discontinued the manufacture of Valproate Sodium Injection, 500mg/5mL (100mg/mL), in 1-count single-dose vials (NDC #70860-784-41).

***Note:*** This product's label and manufacture is from Athenex Pharmaceutical Division, LLC, who are now owned by Sagent.

This product is indicated to treat various types of seizure disorders.

### Vecuronium Bromide Injection By Fresenius Kabi

On March 22, the FDA announced that Fresenius Medical Care North America of Waltham, Massachusetts has discontinued the manufacture of Vecuronium Bromide Injection 1mg/mL, in the following size vials.

- **10mg:** In 10-count packages (NDC #63323-781-10).
- **20mg:** In 10-count packages (NDC #63323-782-20).

This product is indicated to relax the muscles before anesthesia, in preparation for surgery.

### Vibramycin® Capsules

On February 1, the FDA announced that Pfizer Inc. of New York City has discontinued the manufacture of Vibramycin® (doxycycline hyclate) Capsules 100mg, in 50-count bottles (NDC #0069-0950-50).

# Outstanding Buyer Nominee - Kelly Kline

***What is the nominee's name, job title, facility name, and location?*** **Kelly Kline,** CPhT-Adv., Pharmacy Buyer, Atlantic General Hospital, Berlin, Maryland.

***As a nominating third party, please provide your own name, title, facility, and relationship to the nominee.*** **Michael Geesaman**, PharmD, Pharmacy Operations Supervisor at Atlantic General Hospital. I am Kelly's supervisor.

***Is the nominee certified, licensed, and/or registered, as a Pharmacy Technician in their state?*** Yes, the nominee Kelly is both a Certified and Licensed Technician.

***Is the nominee a current NPPA member, and will be current through this August?*** Yes, Kelly is an NPPA member and will be current through this August.

***What is the number of beds at the nominee's facility, and what type of facility is it? (Teaching vs. community, rural vs. urban, etc.)*** 60-bed rural community hospital.

***Approximately how many dollars per year of pharmaceutical-related expenditures does the nominee purchase or supervise the purchasing of at the nominee's facility?*** $4 million.

***What is the average dollar amount of pharmacy inventory the nominee controls each year?*** Approximately $750,000 for our facility.

***Additional comments by the nominee, Kelly Kline:*** To clarify, the inventory at my facility's inpatient pharmacy (Atlantic General Hospital) is about $750,000. However, I also oversee inventory for the rest of our health system as well as our Cancer Center, which then all comes to somewhere between $1 million to $2 million in inventory dollars that I manage.

***What is the nominee's/Pharmacy Department's current Inventory "Turns"?*** 5 turns (for Atlantic General alone).

***How long has the nominee been a Pharmacy Buyer?*** Overall, Kelly has been a pharmacy buyer for 13 years. Here at Atlantic General, she has been the buyer for 3 years.

*Continued on Page 18*

# Discontinued Drugs

*Continued from Page 16*

This product is indicated only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

**Zithromax® Oral Suspension**

On February 28 and March 26, the FDA announced that Pfizer Inc. of New York City has made a business decision to discontinue the manufacture of Zithromax® (azithromycin) Oral Suspension, as follows.

- **200mg/5mL:** In 1,200mg bottles (30mL when mixed), cherry flavored (NDC #0069-3140-19).
- **1Gm:** In boxes of 3 single-dose packets (NDC # 0069-3051-75).

Zithromax is an antibiotic indicated to fight bacteria. It is also used to treat many different types of infections caused by bacteria, such as respiratory infections, skin infections, ear infections, eye infections, and sexually transmitted diseases.

**Zolpidem Tartrate Extended-Release Tablets (C-IV) By Sandoz**

On January 26, the FDA announced that Sandoz Inc. of Princeton, New Jersey has discontinued their manufacture of Zolpidem Tartrate Extended-Release Tablets, in the following strengths.

- **6.25mg:** In 100-count bottles (NDC #0781-5315-01).
- **12.5mg:** In 100-count bottles (NDC #0781-5316-01).

Zolpidem Tartrate has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 4 (C-IV) controlled drug substance. It is indicated for the short-term treatment of insomnia, characterized by difficulties with sleep onset and/or maintenance.

**Zyvox® 600mg Tablets**

On March 28, the FDA announced that Pfizer Inc. of New York City has discontinued Zyvox® (linezolid) Tablets 600mg in 30-count unit dose packages (NDC #0009-5138-03).

This product is an antibiotic indicated to treat different types of bacterial infections, such as pneumonia, skin infections, and those that are resistant to other antibiotics.

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# Outstanding Buyer, Kline

*Continued from Page 17*

***What are the nominee's primary responsibilities as a Pharmacy Buyer and otherwise?***

- Managing the inpatient pharmacy inventory including drug shortages, recalls, and outdates.
- Supporting over 20 doctor's offices in medication acquisition.
- Working as a superuser and primary trainer for staff on Pyxis™ and Pyxis Logistics.
- Reporting to pharmacy leadership on inventory dollars, vend/refill ratios, stockouts, cost-saving opportunities, and other Key Performance Indicators (KPIs).
- Leading our initiative to implement Radio-Frequency Identification (RFID) technology into our med trays.

***What may be unique or challenging about the nominee's facility?*** Atlantic General Hospital is within a resort community where our base population is approximately 7,000 in the offseason but swells to over 300,000 during the summer. With such a large variation, we see a large contrast in medication needs and inventory volume.

***List any accomplishments or projects the nominee instituted that have either saved money for their department/facility or helped to make their job or the department/facility run more efficiently.***

Since 2021, Kelly has reduced on-hand inventory dollars by 40% or about $300,000. She has fine-tuned the inventory in our automated dispensing devices such as Pyxis, so that 90% or more of all medication needed comes from those automated devices and not the main pharmacy. In addition, Kelly is LEAN certified.

***How has the nominee's job changed over the years?*** Kelly is leading our effort to be compliant with the Drug Supply Chain Security Act (DSCSA). Our pharmacy recently moved to a perpetual-inventory system versus using a scheduled quarterly inventory. This provides real-time inventory dollars but also requires significant upkeep, led by Kelly. She is then able to report back to senior leadership with the progress on reducing inventory dollars and reducing days on hand to reach our goal numbers. In addition, Kelly has led the training and implementation of RFID technology for our inventory.

***What does the nominee like about their job?*** Kelly enjoys the challenge of procuring medications which may be in short supply or allocated. Pioneering the way for the other techs in researching advanced certifications that enhance her skills and knowledge while also allowing her to practice at a higher level. She is great at using the tools at her disposal to optimize the inventory. She examines the work being done by her fellow pharmacy techs and makes their job easier by adjusting medication pars, locations, and finding alternative meds.

***What does the nominee dislike about their job?*** When a medication is backordered, Kelly takes it upon herself to find a resolution. While no one likes dealing with backorders and recalls, she always finds a way to work with the pharmacists and providers to ensure we have alternatives available to provide great patient care, regardless of the circumstances.

***What advice would the nominee have for drug company vendor representatives?*** Kelly kindly asks them to not call so often; email is the preferred method of contact so that she can respond when possible due to her busy schedule. Also, for security and scheduling purposes she politely asks drug company reps to make appointments.

***What specific challenges does the nominee face on the job?*** Navigating drug shortages is the biggest challenge—especially finding the medication needed in sufficient quantity while maintaining contract compliance. Kelly is also on the front line with maintaining our perpetual inventory system and automated dispensing cabinets. New challenges are emerging with DSCSA and Kelly must ensure that the hospital maintains compliance with these new standards. Finally, new USP Chapter 797 requirements also require her to source sterilized cleaning agents and maintain our personal protective equipment (PPE) inventory.

***How has the nominee's NPPA membership helped them in their job and/or personally? (Overall, or from information provided in NPPA's official member-publication Pharmacy Purchasing Outlook.)***

*PPO* is one of Kelly's go-to publications. It is jam-packed with industry news, trends, trivia, and interesting info about people in the pharmacy field. She has adjusted purchasing strategies based on knowledge gained from the publication. The NPPA website also does an excellent job conveying the excitement and relevance of their annual conference.

***Has the nominee ever attended an NPPA Conference? If so, how did that help in their job after the event? If not, what prevented them from attending?*** Kelly has been a member of NPPA since 2022. She attended her first NPPA Conference in 2023. It is *the* Pharmacy Buyer event of the year, and she is excited to be a part of it.

# Outstanding Buyer, Kline

*Continued from Page 18*

***Additional comments by Ms. Kline:*** I attended my first NPPA Conference last year, in 2023; and was also as an Outstanding Buyer of the Year nominee at the time. For this year, I am considering presenting a lecture for the educational program.

***Editorial Note:*** *Ms. Kline is indeed presenting a lecture on this August's educational program of our NPPA Conference, on "Reducing Drug Inventory Costs While Improving Patient Safety & Outcomes: A Team Approach", which also comes with 1 hour of the required continuing education (CE) credit for Patient Safety.*

***If the nominee were one of the top-2 placing awardees for this program, would they be able to attend the upcoming NPPA Conference?*** Yes, Kelly will attend.

***Does the nominee belong to any other professional organizations besides NPPA? If so, are they involved with any of them beyond being a member?***

- Member of Maryland Pharmacist Association (MPhA).
- Awarded MPhA Pharmacy Technician of the Year in 2023.
- Member of the Pharmacy Technician Certification Board (PTCB)
- Has advanced technician credentials with PTCB (as a CPhT-Adv) and is the first and only Pharmacy Tech at our hospital to achieve this goal.
- Panelist for PTCB, who reviews scoring criteria for their tech exams.
- Member of Maryland Society of Health System Pharmacy (MSHP).
- Member of American Association of Pharmacy Technicians (AAPT).
- Member of National Pharmacy Technicians Association (NPTA).

***Additional nominee comments:***

- Member of The Pharmacy Technician Society (TPTS).
- Member of Board of Pharmacy Technician Specialties (BPTS).
- Member of Health Connect Partners (HCP).

***List any other qualifications the nominee may have for this award, such as being recognized by their facility, having an article published, organizing buyer meetings, public speaking, volunteer work, etc.***

- Chosen as the Maryland Pharmacy Technician of the Year award recipient by the MPhA in 2023.
- Awarded several safety ambassador awards by Atlantic General Hospital for going above and beyond what is expected for safe patient care.
- Achieved advanced certifications through PTCB, in medication history, vaccine administration, hazardous meds management, regulatory compliance, supply chain and inventory management.
- Volunteers and fundraises for Make-A-Wish, St. Jude's Hospital, and the American Cancer Society.

***Additional comments by Ms. Kline:***

- I also have advanced certificates from NPTA for pharmacy technician product verification, and from BPTS for controlled substance diversion prevention.
- The Maryland Board of Pharmacy currently has an open technician seat for which I am a nominee.
- A local high school recently invited me to speak during their Career Day.

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# New Drugs/Indications

### Airsupra™ Inhaler For As-Needed Rescue Use & To Reduce Risk Of Asthma Exacerbations - Now Available

On January 23, AstraZeneca of Wilmington, Delaware announced the availability of Airsupra™ (albuterol/budesonide) Inhaler. Airsupra was FDA-approved in January 2023 and is indicated for as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in people with asthma aged 18 years and older (see *January-February 2023 PPO*).

Airsupra is the only FDA-approved, as-needed SABA/ICS asthma rescue available in the U.S. and is designed to treat both symptoms and inflammation. It contains a short-acting beta2-agonist (SABA), to help relax the smooth muscles of the airways, and an inhaled corticosteroid (ICS), to help decrease inflammation in the lungs.

The approach to treating asthma symptoms with rescue has recently changed. The 2023 Global Initiative for Asthma (GINA) report supports a rescue approach that treats both symptoms and inflammation together. Combination SABA/ICS is now recommended as a rescue option for adults with asthma regardless of ICS maintenance medication. According to GINA, recommendations for a change in rescue approach were largely based on the risk associated with SABA-only treatment of asthma.

**Liz Bodin,** VP of U.S. Respiratory & Immunology at AstraZeneca, said: "With Airsupra now available in the U.S., we are taking an important step in our mission to revolutionize asthma for millions of people living with the disease. We are hopeful our innovative asthma rescue medicine can help alleviate the burden by addressing both symptoms and underlying inflammation simultaneously at the right time to reduce the risk of having a severe asthma attack."

### Amtagvi™ Suspension - First Cellular Therapy For Advanced Melanoma

On February 16, Iovance Biotherapeutics, Inc. of San Carolos, California announced the FDA approved Amtagvi™ (lifileucel) Suspension for intravenous (IV) infusion, indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

Amtagvi is the ***first and only*** one-time, individualized T cell therapy to receive FDA approval for a solid tumor cancer. Until now, there have been no FDA-approved treatment options for patients with advanced melanoma whose disease progressed following initial treatment with an immune checkpoint inhibitor and, if appropriate, targeted therapy.

Melanoma is a form of skin cancer that is often caused by exposure to ultraviolet light, which can come from sunlight or indoor tanning. Although melanomas only represent approximately 1% of all skin cancers, they account for a significant number of cancer-related deaths. Melanoma can spread to other parts of the body if not detected and treated early, resulting in metastatic disease. Each year, approximately 8,000 people in the U.S. die from melanoma.

Treatment for unresectable or metastatic melanoma may include immunotherapy using PD-1 inhibitors, which are antibodies targeting certain proteins in the body to help the immune system fight off cancer cells. In addition, drugs targeting the BRAF gene, which helps with managing the growth and functioning of cells, may be used for treating melanoma associated with BRAF gene mutations. Those patients whose melanoma has progressed with these therapies have a high unmet medical need.

Amtagvi offers a new cell therapy approach that deploys patient-specific T cells called tumor infiltrating lymphocyte (TIL) cells. When cancer is detected, the immune system creates TIL cells to locate, attack, and destroy cancer. TIL cells recognize distinctive tumor markers on the cell surface of each person's cancer. When cancer develops and prevails, the body's natural TIL cells can no longer perform their intended function to fight cancer. The drug is manufactured using a proprietary process to collect and expand a patient's unique T cells from a portion of their tumor. Amtagvi returns billions of the patient's T cells back to the body to fight their cancer.

***Note:*** The administration of Amtagvi for patients will be done in Authorized Treatment Centers (ATCs), as part of a combination treatment regimen that includes lymphodepletion and a short course of high-dose Proleukin® (aldesleukin) Injection for IV use (also an Iovance Biotherapeutics product).

**Samantha R. Guild,** J.D., President of the AIM at Melanoma Foundation in Frisco, Texas, said: "The approval of Amtagvi offers hope to those with advanced melanoma who have progressed following initial standard of care therapies, as the current treatment options are not effective for many patients. This one-time cell therapy represents a promising innovation for the melanoma community, and we are excited by its potential to transform care for patients who are in dire need of additional therapeutic options."

The FDA granted Amtagvi with Fast Track, Priority Review, Orphan Drug, and Regenerative Medicine Advanced Therapy designations.

**Peter Marks,** M.D., Ph.D., Director of the FDA's Center for Biologics Evaluation & Research, said: "Unresectable or metastatic

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# New Drugs/Indications

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melanoma is an aggressive form of cancer that can be fatal. The approval of Amtagvi represents the culmination of scientific and clinical research efforts leading to a novel T cell immunotherapy for patients with limited treatment options."

**Breyanzi® Infusion - The First & Only CAR T-Cell Therapy For Relapsed Or Refractory CLL Or SLL**

On March 14, Bristol Myers Squibb of Princeton, New Jersey announced the FDA approved Breyanzi® (lisocabtagene maraleucel) Suspension for intravenous (IV) Infusion, indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma who have received at least two prior lines of therapy, including a Bruton tyrosine kinase inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.

Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are among the most common types of B-cell lymphoma. Treatments for people living with CLL or SLL primarily consist of targeted therapies including (Bruton tyrosine kinase) BTK inhibitors and (B-cell lymphoma 2) BCL-2 inhibitors. However, patients often experience relapse or become refractory following early-line treatment with these therapies and there is no established standard of care for patients with double-class exposed CLL or SLL. After relapsing or becoming refractory to these therapies, patients have few options and poor outcomes, including lack of durable complete responses.

CLL is one of the most common types of leukemia in adults. In CLL, too many blood stem cells in the bone marrow become abnormal lymphocytes, which then have difficulty in fighting infections. As the number of abnormal cells grows, there is less room for healthy white blood cells, red blood cells, and platelets. SLL also affects the lymphocytes, with cancer cells found mostly in the lymph nodes.

While there are several treatments available for CLL and SLL, there is a need for additional effective therapies as there is no standard of care for R/R CLL or SLL after prior therapy with targeted agents, such as BTK and BBCL-2 inhibitors. Patients with R/R disease have limited treatment options and generally experience shorter periods of response with each subsequent treatment.

Breyanzi is delivered as a one-time infusion treatment, made from a patient's own T-cells, which are collected and genetically reengineered to become CAR T-cells. The therapy provides a deep, durable response for patients with relapsed or refractory (R/R) CLL or SLL who have historically had no standard of care. The medication is a CD19-directed chimeric antigen receptor (CAR) T-cell drug with a 4-1BB costimulatory domain, which enhances the expansion and persistence of the CAR T-cells.

**Tanya Siddiqi,** M.D., Associate Professor for the Division of Lymphoma at the City of Hope National Medical Center in Irvine, California (and lead investigator in the drug's clinical trials), said: "CLL and SLL are currently considered incurable diseases with few treatment options in the relapsed setting that can confer complete responses, something that has historically been associated with improved long-term outcomes. The FDA approval of liso-cel in relapsed or refractory CLL and SLL after treatment with prior BTKi and BCL2i is a remarkable breakthrough, shifting the treatment paradigm from continuous therapy with sequential regimens to overcome drug resistance, to a one-time personalized T-cell based approach that has the potential to offer patients complete and lasting remission."

**Combogesic® IV Injection For Non-Opioid Pain Management - Now Available**

On February 5, Hikma Pharmaceuticals USA Inc. of Eatontown, New Jersey announced the ***launch*** of Combogesic® IV (acetaminophen/ibuprofen) Injection 1,000mg/300mg.

This product was originally FDA-approved in October 2023, indicated for use in adults when an IV route of administration is considered clinically necessary for the relief of mild to moderate pain, and the management of moderate to severe pain as an adjunct to opioid analgesics.

Combogesic is an intravenous (IV), opioid-free pain relief medicine for injection, that is a combination of 1,000mg of acetaminophen and 300mg of ibuprofen, a nonsteroidal anti-inflammatory drug (NSAID).

**Duvyzat™ Oral Suspension - First Nonsteroidal Treatment For DMD**

On March 21, Italfarmaco S.p.A. of Milan, Italy announced the FDA approval of Duvyzat™ (givinostat) Oral Suspension, indicated for the treatment of Duchenne muscular dystrophy in patients 6 years or older.

Its recommended dosage is determined by the individual's body weight, and should be administered orally twice daily with food.

Duvyzat is the first nonsteroidal drug approved to treat patients with all genetic variants of Duchenne muscular dystrophy. It is a histone deacetylase (HDAC) inhibitor drug that works by targeting pathogenic processes to reduce inflammation and loss of muscle.

Duchenne muscular dystrophy (DMD) is a severe neuromuscular genetic disease characterized by progressive muscle weakness and

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# New Drugs/Indications

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degeneration and is the most common type of muscular dystrophy globally. DMD is caused by mutations in the dystrophin gene that result in the absence of a functional dystrophin protein. Without it, muscle fibers are highly susceptible to injury and this continuous muscle injury leads to chronic inflammation, impairment of muscle regeneration, and muscle replacement by fibrotic and fat tissue.

Life expectancy for those with DMD has increased over the years, with some patients surviving beyond 30 years. The disease primarily affects boys, with symptoms usually first seen between 2 and 5 years of age. Symptoms worsen over time affecting the ability to walk. Eventually, heart and respiratory muscles are affected, which are the two main causes of premature death. DMD incidence is approximately 1 in every 3,500 to 6,000 male births worldwide.

**Craig M. McDonald,** M.D., Professor for the Department of Pediatrics & Physical Medicine Rehabilitation at the University of California Davis Health in Sacramento (and investigator in the drug's clinical trial), said: "There is a tremendous unmet need for novel therapies in DMD that can achieve meaningful benefits for a broad range of patients. Duvyzat's unique mechanism of action has shown a positive risk/benefit profile and the ability to delay disease progression, supporting its potential to become a key component of the standard of care for people living with DMD."

The FDA granted Duvyzat with Priority Review, Fast Track, Orphan Drug, and Rare Pediatric Disease designations.

### Eohilia™ Oral Suspension - First & Only Treatment For Eosinophilic Esophagitis

On February 12, Takeda Pharmaceutical Co Ltd. of Osaka, Japan (with U.S. headquarters in Cambridge, Massachusetts) announced the FDA approval of Eohilia™ (budesonide) Oral Suspension, the first and only FDA-approved oral therapy indicated for the treatment of eosinophilic esophagitis in patients 11 years of age and older.

Product is available in 2mg/10mL single-dose stick packs.

Its recommended dose is 2mg orally, twice daily for 12 weeks.

Eohilia is a corticosteroid drug that was developed specifically for this indication. Its novel formulation of the steroid budesonide confers thixotropic properties, in that it flows more freely when shaken and returns to a more viscous state when swallowed.

Eosinophilic esophagitis (EoE) is a chronic, immune-mediated, inflammatory disease localized in the esophagus. Although the exact cause is unknown, it is believed to be triggered by a variety of stimuli including certain foods and environmental allergens. The chronic inflammation of EoE can lead to a range of symptoms, which can vary by person and age, and include difficulty swallowing, vomiting, and pain. Identifying EoE can be complex and delayed diagnosis is common among patients. If left untreated, the inflammation of EoE can worsen and narrow the esophagus, which can lead to food impaction (when food becomes stuck in the esophagus). In fact, EoE is the leading cause of emergency room visits for food impaction.

**Ikuo Hirano,** M.D., Professor & Director of the Kenneth C. Griffin Esophageal Center in the Division of Gastroenterology & Hepatology at Northwestern University Feinberg School of Medicine in Chicago, Illinois, said: "Various formulations of corticosteroids have been used in the past to manage EoE, but in an off-label capacity and using multiple delivery options. With Eohilia, it's gratifying to now have an FDA-approved treatment specifically formulated for a consistent dose delivery with demonstrated ability to address esophageal inflammation and EoE dysphagia symptoms. As the treatment needs and goals of patients with EoE can vary, I welcome the flexibility that Eohilia offers as an oral medication."

### Exblifep® Injection For Complicated Urinary Tract Infections

On February 27, Allecra Therapeutics GmbH of Lorrach, Germany announced the FDA approved Exblifep® (cefepime/enmetazobactam) Injection for intravenous (IV) use, indicated as a treatment for complicated urinary tract infections, including pyelonephritis, in patients 18 years and older.

Exblifep is a combination of cefepime (a cephalosporin antibacterial drug), and enmetazobactam (a beta-lactamase inhibitor).

The recommended dose for this indication is 2.5Gm (being 2Gm cefepime and 0.5Gm enmetazobactam) every 8 hours by IV infusion over 2 hours for 7 to 14 days, in patients 18 years of age and older with an estimated glomerular filtration rate (eGFR) between 60mL/min to 129mL/min.

Allecra has also received a 5-year marketing exclusivity extension from the FDA as part of the Generating Antibiotic Incentives Now Act (GAIN Act). The GAIN Act, enacted by the U.S. Congress, incentivizes the creation of new anti-infective therapeutics by providing benefits to manufacturers of Qualified Infectious Disease Products (QIDPs).

**Iain Buchanan,** Supervisory Board Member of Allecra Therapeutics, said: "We value the FDA's positive decision on Exblifep's ability to address a critical unmet medical need for patients with complicated urinary tract infections that can be difficult or recurring."

# New Drugs/Indications

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**Lenmeldy™ Infusion - First & Only Gene Therapy For Pediatric Metachromatic Leukodystrophy**

On March 18, Orchard Therapeutics, Inc. of Boston, Massachusetts (recently acquired by Kyowa Kirin, Inc. of Princeton, New Jersey) announced the FDA approved Lenmeldy™ (atidarsagene autotemcel) Suspension Infusion for intravenous (IV) use, indicated for pre-symptomatic late infantile, pre-symptomatic early juvenile or early symptomatic early juvenile (collectively referred to as early-onset) metachromatic leukodystrophy in children.

Metachromatic leukodystrophy (MLD) is a debilitating, rare genetic disease affecting the brain and nervous system. It is caused by a deficiency of an enzyme called arylsulfatase A (ARSA), leading to a buildup of sulfatides (fatty substances) in the cells. This buildup causes damage to the central and peripheral nervous system, manifesting with loss of motor and cognitive function and early death.

In its most severe form, babies develop normally but in late infancy start to rapidly lose the ability to walk, talk, and interact with the world around them. These children eventually deteriorate into a vegetative state, which may require 24-hour intensive care, and the majority pass away within 5 years of disease onset, creating an enormous emotional and financial burden on the family. It is estimated that MLD affects 1 in every 40,000 individuals in the United States. There is no cure for MLD, and treatment typically focuses on supportive care and symptom management.

Lenmeldy is a one-time, individualized single-dose infusion made from the patient's own hematopoietic (blood) stem cells, which have been genetically modified to include functional copies of the ARSA gene. The stem cells are collected from the patient and modified by adding a functional copy of the ARSA gene. The modified stem cells are transplanted back into the patient where they engraft (attach and multiply) within the bone marrow. The modified stem cells supply the body with myeloid (immune) cells that produce the ARSA enzyme, which helps break down the harmful build-up of sulfatides and may stop the progression of MLD. Prior to treatment, patients must undergo high-dose chemotherapy, a process that removes cells from the bone marrow so they can be replaced with the modified cells in Lenmeldy.

The FDA granted Lenmeldy with Priority Review, Rare Pediatric Disease, and Regenerative Medicine Advanced Therapy designations, as well as a Priority Review Voucher.

**Nicole Verdun,** M.D., Director of the Office of Therapeutic Products in for Biologics Evaluation & Research (CBER), said: "MLD is a devastating disease that profoundly affects the quality of life of patients and their families. Advancements in treatment options offer hope for improved outcomes and the potential to positively influence the trajectory of disease progression. This approval represents important progress in the advancement and availability of effective treatments, including gene therapies, for rare diseases."

**Opsynvi® - First & Only Once-Daily Single-Tablet Combo Therapy For Pulmonary Arterial Hypertension**

On March 22, Johnson & Johnson Services, Inc. of Raritan, New Jersey announced their wholly owned subsidiary, Actelion Pharmaceuticals US, Inc. of South San Francisco, was granted FDA approval for Opsynvi® (macitentan/tadalafil) Tablets, indicated for the chronic treatment of adults with pulmonary arterial hypertension.

The recommended dose is one 10mg/20mg or 10mg/40mg tablet that is taken orally once daily, with or without food.

Pulmonary arterial hypertension (PAH) is a rare, progressive, and life-threatening blood vessel disorder that is characterized by the constriction of small pulmonary arteries and elevated blood pressure in the pulmonary circulation, that eventually leads to right heart failure. An estimated 500 to 1,000 new cases of PAH are diagnosed each year in the U.S., classifying the disease as a rare condition.

Opsynvi is a single-tablet combination of macitentan–an endothelin receptor antagonist (ERA) drug, and tadalafil–a phosphodiesterase 5 (PDE5) inhibitor drug. Opsynvi can be used in patients with pulmonary arterial hypertension who are treatment-naïve or in those who are already on an ERA, PDE5 inhibitor, or both.

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# New Drugs/Indications

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**James F. List,** M.D., Ph.D., Global Therapeutic Area Head, whose team oversees a portfolio of programs including Pulmonary Hypertension at Johnson & Johnson, said: "People with PAH often live with the burden of taking many pills each day, which can pose challenges. We're thrilled to bring this single tablet combination therapy to patients, as it has the potential to optimize disease management and fulfill a significant unmet need in supporting recently updated treatment guidelines that call for initial or early combination treatment."

With this approval, Johnson & Johnson now offers a PAH portfolio addressing all three foundational and guideline-recommended pathways: nitric oxide, endothelin, and prostacyclin.

***Note:*** For all female patients, Opsynvi is only available through a restricted program called the Macitentan-Containing Products Risk Evaluation & Mitigation Strategy (REMS) program, due to the risk of embryo-fetal toxicity during pregnancy.

### Rezdiffra™ Tablets For Noncirrhotic Nonalcoholic Steatohepatitis With Moderate To Advanced Liver Fibrosis

On March 14, Madrigal Pharmaceuticals, Inc. of Conshohocken, Pennsylvania announced the FDA has granted approval of Rezdiffra™ (resmetirom) Capsules, in conjunction with diet and exercise, indicated for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

Note that Rezdiffra is currently only available through a limited specialty pharmacy network.

Noncirrhotic nonalcoholic steatohepatitis (NASH) is a more advanced form of nonalcoholic fatty liver disease. NASH is a leading cause of liver-related mortality and an increasing burden on healthcare systems globally. Additionally, patients with NASH, especially those with more advanced metabolic risk factors (hypertension, concomitant Type 2 diabetes), are at increased risk for adverse cardiovascular events and increased morbidity and mortality.

Approximately 1.5 million patients have been diagnosed with NASH in the U.S., of which approximately 525,000 have NASH with moderate to advanced liver fibrosis. It is also known as metabolic dysfunction associated steatohepatitis (MASH). In 2023, global liver disease medical societies and patient groups came together to rename the disease, with the goal of establishing an affirmative, non-stigmatizing name and diagnosis. Nonalcoholic fatty liver disease (NAFLD) was renamed metabolic dysfunction-associated steatotic liver disease. Then NASH was renamed as MASH, and an overarching term–steatotic liver disease was established to capture multiple types of liver diseases associated with fat buildup in the liver. In addition to liver disease, patients with MASH have at least one related comorbid condition (such as obesity, hypertension, dyslipidemia, or Type 2 diabetes).

Rezdiffra is a once-daily, oral THR-β agonist drug that is designed to target the key underlying causes of noncirrhotic nonalcoholic steatohepatitis.

**Becky Taub,** M.D., Founder, Chief Medical Officer & President of Research & Development for Madrigal, stated: "We believe Rezdiffra will change the treatment paradigm for NASH with moderate to advanced liver fibrosis, giving physicians a liver-directed therapy to help improve fibrosis and resolve NASH before their patients progress to cirrhosis."

### Tevimbra® Injection For Advanced Esophageal Squamous Cell Carcinoma

On March 14, BeiGene, Inc. of Cambridge, Massachusetts announced the FDA approved Tevimbra® (tislelizumab-jsgr) Injection for intravenous (IV) use, indicated as monotherapy for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

Product is expected to be available in the second half of 2024.

Globally, esophageal cancer (EC) is the sixth most common cause of cancer-related deaths. Esophageal squamous cell carcinoma (ESCC) is the most common histologic of EC subtypes, accounting for nearly 90% of ECs. An estimated 957,000 new EC cases are projected in year 2040, which would be an increase of nearly 60% from twenty years prior (in 2020). This significant expected increase underscores the need for additional effective treatments. EC is a rapidly fatal disease, and more than two-thirds of patients have advanced or metastatic disease at the time of diagnosis, with an expected 5-year survival rate of less than 6% for those with distant metastases.

The drug tislelizumab is a uniquely designed humanized immunoglobulin G4 (IgG4) anti-programmed cell death protein 1 (PD-1) monoclonal antibody, with high affinity and binding specificity against PD-1. It is designed to minimize binding to Fc-gamma receptors on macrophages, helping to aid the body's immune cells to detect and fight tumors.

**Syma Iqbal,** M.D., Associate Professor of Clinical Medicine, Section Chief of Gastrointestinal Oncology in the Division of Medical Oncology & Cancer Physician in Chief at Norris Comprehensive Cancer Center and the Keck School of Medicine at the University of Southern California in Los Angeles, said: "Patients

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# New Drugs/Indications

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diagnosed with advanced or metastasized ESCC, the most common histologic subtype of esophageal cancer, often progress following initial therapy and are in need of new options. The clinical drug trial showed that patients with previously treated ESCC who received Tevimbra saw a clinically meaningful survival benefit, highlighting its potential as an important treatment option for these patients."

***Note:*** Women are advised to use effective contraception during treatment with Tevimbra and for 4 months after the last dose.

**Tryvio™ Tablets - First & Only Endothelin Receptor Antagonist For High Blood Pressure Not Adequately Controlled**

On March 20, Idorsia Pharmaceuticals U.S. Inc. of Radnor, Pennsylvania announced the FDA approved Tryvio™ (aprocitentan) Tablets, indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs.

Product is expected to be available in the second half of 2024.

The recommended dosage of Tryvio is 12.5mg orally once daily, with or without food.

Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions. Tryvio is an endothelin receptor antagonist that inhibits the binding of endothelin (ET)-1 to ETA and ETB receptors. The effects of ET-1 bear many similarities with the pathophysiology of hypertension, and ET-1 is a major driver of aldosterone production.

Until the approval of Tryvio, no systemic antihypertensive medications targeted the ET pathway, as approved antihypertensive therapies focus on the regulation of salt and water (diuretics), antagonism of the renin-angiotensinaldosterone (RAAS) system, reduction of influx of extracellular calcium into the cell (calcium channel blockers), sympatholytic activity (beta blockers, central alpha-agonist agents), or nonselective vasodilatory effects.

**Michael A. Weber,** M.D., Professor of Medicine in the Division of Cardiovascular Medicine State University of New York in Brooklyn and an investigator in the clinical study), commented: "Today, we are not able to reduce blood pressure below recommended levels in at least 10% of the hypertensive patients we treat. As well, it is often patients at high risk of adverse cardiovascular outcomes and typically with comorbidities who pose this challenge. We have had to wait for over 30 years to see the approval of an oral anti-hypertensive agent that works on a new therapeutic pathway, so Tryvio provides transformational progress in the field of systemic hypertension. It is taken as a single daily oral dose that works in combination with whatever other drugs are being prescribed and without drug-drug interactions in patients with the burden of uncontrolled hypertension. Tryvio is easy for physicians to prescribe and easy for patients to use."

***Note:*** Tryvio is available only through a restricted program called the Tryvio Risk Evaluation & Mitigation Strategy (REMS) because of the risk of embryo-fetal toxicity during pregnancy in women.

**Vafseo® For Anemia Due To Chronic Kidney Disease In Dialysis Patients**

On March 27, Akebia Therapeutics®, Inc. of Cambridge, Massachusetts announced the FDA approved Vafseo® (vadadustat) Tablets, indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least 3 months.

Approximately 500,000 adult patients in the U.S. on dialysis suffer from anemia due to chronic kidney disease (CKD), which may be associated with many adverse clinical outcomes. The burden of managing uncontrolled anemia in CKD patients can be substantial, both in terms of healthcare costs and the impact on patients, healthcare providers, and caregivers. Today, most CKD patients are treated for anemia with injectable erythropoiesis-stimulating agents mostly administered at dialysis centers.

Anemia is a condition in which a person lacks enough healthy red blood cells to carry adequate oxygen to the body's tissues. It commonly occurs in people with CKD because their kidneys do not produce enough erythropoietin, a hormone that helps regulate production of red blood cells. Anemia due to CKD can have a profound impact on a person's quality of life as it can cause fatigue, dizziness, shortness of breath, and cognitive dysfunction. Left untreated, anemia leads to deterioration in health and is associated with increased mortality in people with CKD.

Vafseo is a once-daily oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor drug. It activates the physiologic response to hypoxia to stimulate the endogenous production of erythropoietin, in order to manage anemia.

**John P. Butler,** CEO of Akebia, said: "We're proud to deliver an alternative treatment option for the hundreds of thousands of Americans on dialysis who are diagnosed with anemia due to CKD. Our product launch will be designed to drive Vafseo toward a potential new oral standard of care for dialysis patients."

***Note:*** Vafseo may cause harm to an infant, so breastfeeding is not recommended until 2 days after the final dose of Vasfeo.

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# New Drugs/Indications

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### Winrevair™ Injection - New First-In-Class Therapy For Pulmonary Arterial Hypertension

On March 26, Merck & Co., Inc. Rahway, New Jersey announced the FDA approved Winrevair™ (sotatercept-csrk) Injection 45mg and 60mg for subcutaneous use, indicated for the treatment of adults with pulmonary arterial hypertension (World Health Organization Group 1) to increase exercise capacity, improve functional class, and reduce the risk of clinical worsening events. Product is now available.

The medication should be given once every 3 weeks by subcutaneous injection, and can be administered by appropriate patients or caregivers, after guidance, training, and follow-up from a healthcare provider.

Winrevair is the first FDA-approved activin signaling inhibitor therapy for pulmonary arterial hypertension (PAH), representing a new class of therapy that works by improving the balance between pro- and anti-proliferative signaling to regulate vascular cell proliferation underlying PAH.

**Marc Humbert,** M.D., Ph.D., Professor of Medicine & Director of the Pulmonary Hypertension Reference Center at the Université Paris-Saclay in France (and investigator in the drug's clinical trial), said: "Pulmonary arterial hypertension is a rare, progressive, and ultimately life-threatening disease in which blood vessels in the lungs thicken and narrow, causing significant strain on the heart. Based on the clinical trial, adding Winrevair to background PAH therapy demonstrated significant clinical benefits compared to background PAH therapy alone. This approval is an important milestone, as it offers healthcare providers a novel therapeutic option that targets a new PAH treatment pathway."

The FDA granted Winrevair with Breakthrough Therapy designation for this indication.

***Note:*** Winrevair may cause fetal harm when administered to a pregnant woman, thus women should use an effective method of contraception during its treatment and for at least 4 months after the final dose.

Winrevair has been made commercially available to Merck via a licensing agreement with Bristol Myers Squibb.

### Xaciato™ Vaginal Gel For Bacterial Vaginosis - Now Available

On January 10, Daré Bioscience, Inc. of San Diego, California and Organon & Co. of Jersey City, New Jersey jointly announced the launch of Xaciato™ (clindamycin phosphate) Vaginal Gel 2%, indicated to treat bacterial vaginosis in females 12 years and older.

A single-dose user-filled disposable applicator delivers 5Gm of colorless vaginal gel containing 100mg of clindamycin that can be applied at any time of day.

Bacterial vaginosis (BV) is the most common vaginal condition in women of reproductive age in the United States. The condition results from an overgrowth of certain bacteria, which upsets the balance of the natural vaginal microbiome and can lead to symptoms of odor or discharge. BV may self-resolve in up to 30% of women, but most symptomatic women require treatment. If left untreated, BV may lead to serious complications. It has also been shown to disproportionately affect non-Hispanic Black and Mexican American women.

Xaciato is formulated with the goal of limiting leakage and increasing vaginal retention time, since the gel increases its viscosity (thickness and stickiness) at body temperature and gradually releases clindamycin over time.

**Erica Montes,** M.D., Board-Certified Obstetrician & Gynecologist and Fellow of the American College of OB/GYN of Scottsdale, Arizona, explained: "Bacterial vaginosis is the most common form of vaginitis, disrupting the lives of approximately 21 million women. For these women, it's important to consider her individual treatment needs, such as route of administration, cost, adverse events, dosing, and duration of treatment. The availability of Xaciato is important as it's one dose for women experiencing BV and it can be taken at any time of day."

In March 2022, Daré entered into a global exclusive license agreement with Organon for the commercial marketing of Xaciato.

### Zelsuvmi™ Topical Gel For Molluscum Contagiosum

On January 5, Ligand Pharmaceuticals Inc. of San Diego, California announced the FDA approval of Zelsuvmi™ (berdazimer) Topical Gel 10.3%, indicated for the treatment of molluscum contagiosum (molluscum) in adults and pediatric patients one year of age and older. Product is now available.

Zelsuvmi is the first and only topical prescription medication that can be applied by patients, parents, or caregivers at home, outside of a physician's office or other medical setting, to more easily and safely treat this highly contagious viral skin infection.

Molluscum is a highly contagious viral skin infection characterized by skin-colored to red lesions with a central, umbilicated viral core. Approximately 6 million Americans, primarily children, are infected each year. However, up to 73% of children go untreated. Treating the lesions is critical to preventing the viral infection from spreading to other people or to other areas of the body.

# New Drugs/Indications

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Zelsuvmi is a nitric oxide releasing agent, which has been shown to have antiviral properties. The mechanism of action of Zelsuvmi for the treatment of molluscum contagiosum is unknown.

**Stephen W. Stripling,** M.D., Pediatrician and Molluscum Researcher for Coastal Pediatric Associates in Summerville, South Carolina (and study investigator in the drug's clinical trial), said: "It is nice to see that molluscum contagiosum is finally getting the attention it deserves. For those of us in the primary care field, it is wonderful to have an effective option that can be used at home rather than taking a wait and watch approach."

**New Drug Indications/Expanded Approvals**

### Acthar® Single-Dose Pre-Filled Selfject™ Injector - New Route Of Administration

On March 1, Mallinckrodt plc of Dublin, Ireland (with U.S. headquarters in St Louis, Missouri) announced the FDA approval of a supplemental New Drug Application (sNDA) of a ***new route of administration*** for Acthar® Gel (repository corticotropin) SelfJect™ Injector, a single-dose pre-filled injection for intramuscular or subcutaneous use, indicated for appropriate patients with a range of chronic and acute inflammatory and autoimmune conditions.

Product is expected to be available in the third quarter of 2024.

Acthar Gel is now the first in its class to offer a self-controlled, pre-filled delivery device for appropriate patients with a range of chronic and acute inflammatory and autoimmune conditions. Acthar Gel is a naturally sourced complex mixture of adrenocorticotropic hormone analog drugs and other pituitary peptides.

The delivery device is pre-filled with the prescribed dose of Acthar Gel in 40-unit or 80-unit versions. It is designed to help patients with dexterity issues, and has additional safety features including a hidden needle to help protect patients against needlestick injury.

SelfJect is intended to provide the appropriate subcutaneous dose of Acthar Gel, as prescribed by a healthcare professional, and is designed to help give patients control of their administration and may allow some to self-administer with fewer steps.

Acthar Gel will also continue to be available as an injection with a vial and syringe.

### Aurlumyn™ Injection To Treat Severe Frostbite - New Indication

On February 14, the FDA announced the approval of a ***new indication*** for Aurlumyn™ (iloprost) Injection by Eicos Sciences, Inc. of San Mateo, California, now also for the treatment of severe frostbite in adults to reduce the risk of finger or toe amputation.

Frostbite can occur in several stages, ranging from mild frostbite that does not require medical intervention and does not cause permanent skin damage, to severe frostbite when both the skin and underlying tissue are frozen and blood flow is stopped, sometimes requiring amputation.

The active ingredient in Aurlumyn is a vasodilator drug (which opens blood vessels) and prevents blood from clotting. Frostbite can affect military personnel operating in cold regions, industrial workers, people experiencing homelessness, as well as people engaging in recreational activities such as skiing, hiking, mountaineering, and ice climbing.

The FDA granted Aurlumyn for this indication, with Priority Review and an Orphan Drug designation.

**Norman Stockbridge,** M.D., Ph.D., Director of the Division of Cardiology & Nephrology in the FDA's Center for Drug Evaluation & Research, said: "This approval provides patients with the first-ever treatment option for severe frostbite. Having this new option provides physicians with a tool that will help prevent the lifechanging amputation of one's frostbitten fingers or toes."

Iloprost was originally FDA-approved in 2004, to treat pulmonary arterial hypertension.

### Biktarvy® For HIV With Suppressed Viral Loads - Expanded Indication

On February 26, Gilead Sciences, Inc. of Foster City, California announced the FDA approved an ***expanded indication*** for Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide, or B/F/TAF) Tablets 50mg/200mg/25mg, now also to treat people with human immunodeficiency virus (HIV) who have suppressed viral loads with known or suspected M184V/I resistance, a common form of treatment resistance.

HIV treatment resistance is permanent and irreversible, which can jeopardize future treatment options for patients. The M184V/I resistance mutation has been found to be present in a range (22% to 63%) of patients with HIV with pre-existing resistance to nucleoside reverse transcriptase inhibitors (NRTIs) across various HIV subtypes.

Biktarvy is now the first and only integrase strand transfer inhibitor (INSTI)-based single-tablet regimen that is both FDA approved and U.S. Department of Health & Human Services (HHS) guideline recommended for patients with HIV who are virally suppressed with M184V/I resistance.

Once someone with HIV has developed resis-

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# New Drugs/Indications

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tance to a treatment, it will persist for the rest of their life. Reducing the risk of drug resistance is a key goal in HIV therapy. HIV drug resistance continues to receive clinical and public health attention because it may hinder the ability of HIV medicines to suppress and block replication of the virus over the course of an individual's life. Resistance may lead to treatment failure in individuals, while also creating the potential for transmission of treatment-resistant HIV within communities.

Biktarvy is a complete HIV treatment that combines three powerful medicines to form the smallest 3-drug, integrase strand transfer inhibitor-based single-tablet regimen available, offering simple once-daily dosing with or without food, with a limited drug interaction potential and a high barrier to resistance.

Note: Biktarvy is a complete single-tablet regimen and should not be taken with other HIV medicines.

**Paul E. Sax,** M.D., Clinical Director for the Division of Infectious Diseases at Brigham & Women's Hospital and Professor of Medicine at Harvard Medical School in Boston, Massachusetts, said: "Treatment failure in HIV must be avoided whenever possible, so a high barrier to resistance should be standard of care to maximize the chances of durable virologic suppression. This label update builds on the established high resistance barrier of Biktarvy by showing that it's effective in patients with HIV who may have certain forms of pre-existing resistance or a history of past treatment failure."

### Brukinsa® Capsules For Relapsed Or Refractory Follicular Lymphoma - Expanded Indication

On March 7, BeiGene USA, Inc. of Cambridge, Massachusetts announced the FDA approved an ***expanded indication*** for Brukinsa® (zanubrutinib) Capsules, now also for the treatment of adult patients with relapsed or refractory follicular lymphoma, in combination with the anti-CD20 monoclonal antibody obinutuzumab, after two or more lines of systemic therapy.

Follicular lymphoma (FL) is the second most common type of non-Hodgkin lymphoma (NHL), accounting for 22% of all NHL cases. Approximately 15,000 cases are diagnosed in the U.S. each year. While FL remains incurable, people with the condition can live a long time. The five-year survival rate is about 90%, and approximately half of people diagnosed with FL can live with the disease for nearly 20 years.

Brukinsa is a small molecule inhibitor of Bruton's tyrosine kinase (BTK) designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared with other approved BTK inhibitors, Brukinsa has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease-relevant tissues.

**Mehrdad Mobasher,** M.D., M.P.H., Chief Medical Officer of Hematology at BeiGene, said: "This approval of Brukinsa represents an important advancement, offering the first and only BTK inhibitor treatment for follicular lymphoma patients in the U.S. who have either not responded to initial therapies or have experienced relapse. Brukinsa is the only BTK inhibitor to date that shows efficacy with this type of malignancy and now has the broadest label, including five oncology indications, of any medication in its class globally. We reaffirm our continued commitment to bringing this much-needed treatment option to patients around the world."

### Casgevy™ Infusion For Transfusion-Dependent Beta Thalassemia - New Indication

On January 16, Vertex Pharmaceuticals Inc. of Boston, Massachusetts announced the FDA approved a ***new indication*** Casgevy™ (exagamglogene autotemcel, exa-cel) Suspension for intravenous (IV) infusion, a CRISPR/Cas9 gene-edited cell therapy now also for the treatment of transfusion-dependent beta thalassemia in patients 12 years and older.

Note: Since the administration of Casgevy requires experience in stem cell transplantation, Vertex is engaging with experienced hospitals to establish a network of independently operated, authorized treatment centers (ATCs) throughout the U.S. to offer Casgevy to patients. All ATCs are able to offer Casgevy to eligible patients with transfusion-dependent beta thalassemia and sickle cell disease.

Transfusion-dependent beta thalassemia (TDT) is a serious, life-threatening genetic disease, whose patients report health-related quality of life scores below the general population. The lifetime healthcare costs of managing TDT in the U.S. are estimated between $5 and $5.7 million. TDT requires frequent blood transfusions and iron chelation therapy throughout a person's life. Due to anemia, patients living with TDT may experience fatigue and shortness of breath, and infants may develop failure to thrive, jaundice, and feeding problems. Complications of TDT can also include an enlarged spleen, liver and/or heart, misshapen bones, and delayed puberty. TDT requires lifelong treatment and significant use of healthcare resources, and ultimately results

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# New Drugs/Indications

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in reduced life expectancy, decreased quality of life, and reduced lifetime earnings and productivity. In the U.S., the median age of death for patients living with TDT is 37 years. Stem cell transplant from a matched donor is a curative option but is only available to a small fraction of people living with TDT because of the lack of available donors.

Casgevy is a non-viral, ex vivo CRISPR/Cas9 gene-edited cell therapy for eligible patients with sickle cell disease or TDT, in which a patient's own hematopoietic stem and progenitor cells are edited at the erythroid specific enhancer region of the BCL11A gene through a precise double-strand break. This edit results in the production of high levels of fetal hemoglobin (HbF; hemoglobin F) in red blood cells. HbF is the form of the oxygen-carrying hemoglobin that is naturally present during fetal development, which then switches to the adult form of hemoglobin after birth. Casgevy has been shown to reduce or eliminate vaso-occlusive crises (VOCs) for patients with sickle cell disease and transfusion requirements for TDT patients.

**Reshma Kewalramani,** M.D., CEO & President of Vertex, said: "On the heels of the historic FDA approval of Casgevy for sickle cell disease, it is exciting to now secure approval for TDT well ahead of its Prescription Drug User Fee Act date. TDT patients deserve new, potentially curative treatment options, and we look forward to bringing Casgevy to eligible patients who are waiting."

### Definity® Injection For Pediatric Patients - Expanded Indication

On March 4, Lantheus Holdings, Inc. of North Billerica, Massachusetts announced the FDA approved the supplemental New Drug Application (sNDA) for Definity® (perflutren lipid microsphere) Suspension for intravenous (IV) Injection, as an ultrasound enhancing agent now also indicated for use in pediatric patients with suboptimal echocardiograms.

This approval represents a significant step forward in pediatric medicine, providing healthcare professionals with a valuable tool to opacify the left ventricular chamber and better identify the left ventricular endocardial border. Currently, Definity is the most utilized, extensively studied, and a trusted diagnostic ultrasound enhancing agent in the United States.

Definity is the most utilized, extensively studied and a trusted ultrasound enhancing agent, with more than 20 years in the market before this.

**Kassa Darge,** M.D., Ph.D., Radiologist-In-Chief & Chair of the Department of Radiology at Children's Hospital of Philadelphia, Pennsylvania, said: "While Definity has long demonstrated its effectiveness in providing better outcomes in adults over the past two decades, this new FDA decision offers a critical diagnostic tool for pediatric heart patients and their families. This approval will offer a valuable alternative to pediatric cardiologists trying to do imaging work up in challenging pediatric cardiac cases."

### Dovato Tablets For Adolescents Living With HIV - Expanded Indication

On April 8, ViiV Healthcare Co of Research Triangle Park, North Carolina announced the FDA has approved an ***expanded indication*** for Dovato (dolutegravir/lamivudine) Tablets, now also for the treatment of HIV-1 infection in adolescents 12 years of age and older and weighing at least 25kg with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Dovato.

In the U.S., 20% of new HIV diagnoses in 2020 were among young people aged 13 to 24. This expanded indication marks the first time an oral, two-drug (2DR), single-tablet regimen is available for adolescents between 12 and 18 year olds living with HIV.

Dovato is a once-daily, oral, two-drug combination in a single-tablet regimen that combines the integrase strand transfer inhibitor (INSTI) dolutegravir (50mg) with the nucleoside reverse transcriptase inhibitor (NRTI) lamivudine (300mg). The two medicines work to inhibit the viral life cycle at two different sites in the body. INSTI drugs (such as dolutegravir) inhibit HIV integrase by binding to the integrase

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active site and blocking the strand transfer step of retroviral DNA integration, which is essential for the HIV replication cycle. NRTIs (such as Lamivudine) has an principal mode of action to inhibit reverse transcriptase via DNA chain termination.

**Lynn Baxter,** Head of North America at ViiV Healthcare, said: "This expanded indication brings an oral, two-drug, single-tablet regimen to adolescents with HIV, providing a complete HIV therapy with fewer ARV medicines–an important consideration for young people who will require lifelong treatment."

### Dupixent® Injection As First & Only Treatment For Pediatric Eosinophilic Esophagitis - Expanded Indication

On January 25, Regeneron Pharmaceuticals, Inc., of Tarrytown, New York and Sanofi US of Bridgewater, New Jersey jointly announced the FDA approved an ***expanded indication*** for Dupixent® (dupilumab) Injection for subcutaneous use, now also for the treatment of pediatric patients aged 1 to 11 years, weighing at least 15kg, with eosinophilic esophagitis.

This product is now the ***first and only*** medicine approved in the U.S. specifically indicated to treat these patients. The approval expands the drug's initial FDA approval for eosinophilic esophagitis in May 2022 for patients aged 12 years and older weighing at least 40kg. The FDA evaluated Dupixent for this expanded indication under Priority Review, which is reserved for medicines that represent potentially significant improvements in efficacy or safety in treating serious conditions.

Eosinophilic esophagitis (EoE) is a chronic, progressive disease associated with type 2 inflammation that is thought to be responsible for damaging the esophagus and impairing its function. EoE can severely impact a child's ability to eat, and they may experience heartburn, vomiting, abdominal discomfort, trouble swallowing, food refusal, and failure to thrive. These symptoms can adversely impact their growth and development. Continuous treatment of EoE may be needed to reduce the risk of complications and disease progression. Approximately 21,000 children under the age of 12 in the U.S. are currently being treated for EoE with unapproved therapies. However, the actual prevalence of children with this disease is likely higher, given symptoms can be mistaken for other conditions and there are delays in diagnosis.

Dupixent, which was invented using Regeneron's proprietary VelocImmune® technology, is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) pathways and is not an immunosuppressant. The Dupixent development program has shown significant clinical benefit and a decrease in type 2 inflammation in Phase 3 trials, establishing that IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases. These diseases include approved indications for Dupixent, such as atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, prurigo nodularis, and EoE. The VelocImmune technology utilizes a proprietary genetically engineered mouse platform endowed with a genetically humanized immune system to produce optimized fully human antibodies.

**George D. Yancopoulos,** M.D., Ph.D., Board Co-Chair, President & Chief Scientific Officer at Regeneron, and a principal inventor of Dupixent, said: "Young children are some of the most vulnerable patients with eosinophilic esophagitis, or EoE, as this debilitating and progressive disease threatens their basic ability to eat. Until now, these children had no approved treatment options specifically for EoE, leaving many with unapproved medicines that failed to target the root cause of their disease. With this approval, Dupixent becomes the first and only treatment option for EoE patients aged 1 and older, weighing at least 15kg. By targeting the underlying type 2 inflammation that contributes to this disease, Dupixent has the potential to transform the standard of care for these children as it has for adults and adolescents with EoE."

### Gammagard Liquid® For Chronic Inflammatory Demyelinating Polyneuropathy - New Indication

On January 29, Takeda Pharmaceuticals U.S.A., Inc. of Cambridge, Massachusetts announced the FDA approved a ***new indication*** for Gammagard Liquid® (immune globulin infusion–human, 10% solution), now also as an intravenous immunoglobulin therapy to improve neuromuscular disability and impairment in

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adults with chronic inflammatory demyelinating polyneuropathy. It can be used as induction therapy, which includes an induction dose followed by maintenance doses.

Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare, acquired, immune-mediated neuromuscular disorder affecting the peripheral nervous system. It is characterized by progressive, symmetric symptoms such as weakness, tingling or loss of feeling in distal and proximal limbs, loss of reflexes and difficulty walking. Because its symptoms may overlap with other rare, neuromuscular conditions, CIDP may be misdiagnosed. The mechanism of action of immunoglobulins in the treatment of CIDP in adults has not been fully elucidated but may include immunomodulatory effects.

Gammagard Liquid is the only intravenous immunoglobulin (IVIG) with multiple neuromuscular disorder indications in the U.S., since it is now approved for CIDP and it is the only FDA-approved IVIG to treat multifocal motor neuropathy as a maintenance therapy to improve muscle strength and disability in adults. It is also indicated in the U.S. as a replacement therapy for people 2 years of age or older living with primary immunodeficiency.

**Mamatha Pasnoor,** M.D., Professor in the Department of Neurology at the University of Kansas Medical Center in Kansas City, said: "As the standard of care for the treatment of CIDP, IG therapy is thought to help normalize compromised immune systems through immunomodulatory mechanisms. Because CIDP is a progressive and complex disease, multiple treatment options are needed, and clinicians now have an additional therapy that can help adults with CIDP manage their disease."

### Hyqvia® Solution As Maintenance Therapy For Chronic Inflammatory Demyelinating Polyneuropathy - New Indication

On January 16, Takeda Pharmaceuticals U.S.A., Inc. of Cambridge, Massachusetts and Halozyme Therapeutics, Inc. of San Diego, California jointly announced the FDA approved a ***new indication*** for Hyqvia® (immune globulin infusion 10%–human, with recombinant human hyaluronidase) Solution for subcutaneous administration, now also for the treatment of chronic inflammatory demyelinating polyneuropathy as maintenance therapy to prevent the relapse of neuromuscular disability and impairment in adults.

Hyqvia is the only FDA-approved combination of immunoglobulin (IG) and hyaluronidase, which makes it a facilitated subcutaneous immunoglobulin (SCIG) infusion. For adults, Hyqvia can be infused up to once monthly (every 2, 3, or 4 weeks) due to the hyaluronidase component of Halozyme's co-formulized Enhanze® drug delivery technology, which facilitates the dispersion and absorption of large immune globulin volumes in the subcutaneous space between the skin and the muscle.

Because it is delivered subcutaneously, Hyqvia can be administered by a healthcare professional in a medical office, infusion center, or at a patient's home. In addition, it can be self-administered after appropriate patient or caregiver training.

Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare, acquired, immune-mediated neuromuscular disorder affecting the peripheral nervous system. It is characterized by progressive, symmetric symptoms such as weakness, tingling or loss of feeling in distal and proximal limbs, loss of reflexes, and difficulty walking. Because its symptoms may overlap with other rare, neuromuscular conditions, it is often misdiagnosed. The role of immune globulin therapy as maintenance treatment in CIDP has been well-established and is the guidelines-based standard of care for this complex condition. However, there are aspects of IVIG treatment that can be challenging for patients such as long treatment duration associated with high immune globulin volumes, potential for venous access challenges, and infusion setting limitations.

Hyqvia contains immune globulin (IG), which are antibodies that maintain the body's immune system, that are collected from human plasma. The hyaluronidase part of Hyqvia facilitates the dispersion and absorption of IG in the subcutaneous space between the skin and the muscle.

**Lisa Butler,** Executive Director of GBS-CIDP Foundation International of Conshohocken, Pennsylvania, said: "While it is considered the standard-of-care for maintenance treatment of adults with CIDP, the IVIG infusions may be challenging for some patients and their caregivers. We're excited that this therapy could offer some adults with CIDP an alternative subcutaneous option that may address some of these challenges and help personalize treatment."

Originally, Hyqvia was FDA-approved in 2014 for the treatment of primary immunodeficiency in adults, which has since been expanded to include children 2 to 16 years old.

### Iclusig® Tablets For Newly Diagnosed Ph+ ALL - New Indication

On March 19, Takeda Pharmaceuticals U.S.A., Inc. of Cambridge, Massachusetts announced the FDA approved a ***new indication*** for Iclusig® (ponatinib) Tablets, now also for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia in combination with chemotherapy.

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# Methylene Blue Injection, USP

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**WARNING: SEROTONIN SYNDROME WITH CONCOMITANT USE OF SEROTONERGIC DRUGS AND OPIOIDS**

**Methylene blue may cause serious or fatal serotonergic syndrome when used in combination with serotonergic drugs and opioids. Avoid concomitant use of methylene blue with selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), and monoamine oxidase inhibitors (MAOIs) and opioids [see Warnings and Precautions and Drug Interactions].**

**Brief Summary of Prescribing Information**
**These highlights do not include all the information needed to use METHYLENE BLUE INJECTION safely and effectively. See full prescribing information for METHYLENE BLUE INJECTION.**

**METHYLENE BLUE Injection, USP for intravenous use**
**Initial U.S. Approval: 2016**

**INDICATIONS AND USAGE:** Methylene blue injection is indicated for the treatment of pediatric and adult patients with acquired methemoglobinemia. This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials *[see Clinical Studies]. Clinical Studies information is approved for PROVEPHARM SAS's Provayblue® (Methylene blue solution, intravenous). However, due to PROVEPHARM SAS's marketing exclusivity rights, this drug product is not labeled with that information.*

**CONTRAINDICATIONS:** Methylene blue is contraindicated in the following conditions: Severe hypersensitivity reactions to methylene blue or any other thiazine dye *[see Warnings and Precautions]*. Patients with glucose-6-phosphate dehydrogenase deficiency (G6PD) due to the risk of hemolytic anemia *[see Warnings and Precautions]*.

**WARNINGS AND PRECAUTIONS:** **Serotonin Syndrome with Concomitant Use of Serotonergic Drugs and Opioids:** The development of serotonin syndrome has been reported with the use of methylene blue class products. Most reports have been associated with concomitant use of serotonergic drugs (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs). Opioids and dextromethorphan may increase the risk of developing serotonin syndrome. Some of the reported cases were fatal. Symptoms associated with serotonin syndrome may include the following combination of signs and symptoms: mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, and hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, and incoordination), seizures, and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Avoid concomitant use of methylene blue with serotonergic drugs and opioids. Patients treated with methylene blue should be monitored for the emergence of serotonin syndrome. If symptoms of serotonin syndrome occur, discontinue use of methylene blue, and initiate supportive treatment. Inform patients of the increased risk of serotonin syndrome and advise them to not to take serotonergic drugs within 72 hours after the last dose of methylene blue injection *[see Drug Interactions, Patient Counseling Information]*. **Hypersensitivity:** Anaphylactic reactions to methylene blue class products have been reported. Patients treated with methylene blue should be monitored for anaphylaxis. If anaphylaxis or other severe hypersensitivity reactions (e.g., angioedema, urticaria, bronchospasm) should occur, discontinue use of methylene blue and initiate supportive treatment. Methylene blue is contraindicated in patients who have experienced anaphylaxis or other severe hypersensitivity reactions to a methylene blue class product in the past. **Lack of Effectiveness:** Methemoglobinemia may not resolve or may rebound after response to treatment with methylene blue in patients with methemoglobinemia due to aryl amines such as aniline or sulfa drugs such as dapsone. Monitor response to therapy with methylene blue through resolution of methemoglobinemia. If methemoglobinemia does not respond to 2 doses of methylene blue injection or if methemoglobinemia rebounds after a response, consider additional treatment options *[see Dosage and Administration]*. Patients with glucose-6-phosphate dehydrogenase deficiency may not reduce methylene blue to its active form in vivo. Methylene blue may not be effective in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. **Hemolytic Anemia:** Hemolysis can occur during treatment of methemoglobinemia with methylene blue. Laboratory testing may show Heinz bodies, elevated indirect bilirubin and low haptoglobin, but the Coombs test is negative. The onset of anemia may be delayed 1 or more days after treatment with methylene blue injection. The anemia may require red blood cell transfusions *[see Adverse Reactions]*. Use the lowest effective number of doses of methylene blue injection to treat methemoglobinemia. Discontinue methylene blue and consider alternative treatments of methemoglobinemia if severe hemolysis occurs. Treatment of patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency with methylene blue may result in severe hemolysis and severe anemia. Methylene blue is contraindicated for use in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency *[see Contraindications]*. **Interference with In Vivo Monitoring Devices:** *Inaccurate Pulse Oximeter Readings:* The presence of methylene blue in the blood may result in an underestimation of the oxygen saturation reading by pulse oximetry. If a measure of oxygen saturation is required during or shortly after infusion of methylene blue it is advisable to obtain an arterial blood sample for testing by an alternative method. *Bispectral index monitor:* A fall in the Bispectral Index (BIS) has been reported following administration of methylene blue class products. If methylene blue is administered during surgery, alternative methods for assessing the depth of anesthesia should be employed. **Effects on Ability to Drive and Operate Machinery:** Treatment with methylene blue may cause confusion, dizziness and disturbances in vision *[see Adverse Reactions]*. Advise patients to refrain from driving or engaging in hazardous occupations or activities such as operating heavy or potentially dangerous machinery until such adverse reactions to methylene blue have resolved. **Interference with Laboratory Tests:** Methylene blue is a blue dye which passes freely into the urine and may interfere with the interpretation of any urine test which relies on a blue indicator, such as the dipstick test for leucocyte esterase.

**ADVERSE REACTIONS:** The following adverse reactions are discussed in greater detail in other sections of the labeling:
- Serotonin Syndrome with Concomitant Use of Serotonergic Drugs and Opioids *[see Warnings and Precautions]*
- Anaphylaxis *[see Warnings and Precautions]*
- Lack of Effectiveness *[see Warnings and Precautions]*
- Hemolytic Anemia *[see Warnings and Precautions]*
- Interference with In-Vivo Monitoring Devices *[see Warnings and Precautions]*
- Effects on Ability to Drive and Operate Machinery *[see Warnings and Precautions]*
- Interference with Laboratory Tests *[see Warnings and Precautions]*

**Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of methylene blue was determined in 82 healthy adults of median age of 36 years (range, 19-55 years); 54% were male, and 68% were white. Each individual in the safety population received a single dose of methylene blue 2 mg/kg intravenously. There was one serious adverse reaction reported (syncope due to sinus pauses of 3-14 seconds). The most common (≥2%) moderate or severe adverse reactions were pain in the extremity (56%), headache (7%), feeling hot (6%), syncope (4%), back pain (2%), hyperhidrosis (2%) and nausea (2%). Table 1 lists the adverse reactions of any severity that occurred in at least 2% of individuals who received methylene blue.

**Table 1**
**Adverse Reactions Following Infusion of Methylene Blue Injection 2 mg/kg**

| Adverse Reaction | Any Grade TEAE (n=82) | | Moderate-Severe TEAE (n=82) | |
|---|---|---|---|---|
| Pain in extremity | 69 | 84% | 46 | 56% |
| Chromaturia | 61 | 74% | 0 | |
| Dysgeusia | 16 | 20% | 1 | 1% |
| Feeling hot | 14 | 17% | 5 | 6% |
| Dizziness | 13 | 16% | 4 | 5% |
| Hyperhidrosis | 11 | 13% | 2 | 2% |
| Nausea | 11 | 13% | 2 | 2% |
| Skin discoloration | 11 | 13% | 0 | |
| Headache | 8 | 10% | 6 | 7% |
| Musculoskeletal pain | 7 | 9% | 0 | |
| Paresthesia oral | 7 | 9% | 0 | |
| Paresthesia | 7 | 9% | 0 | |
| Infusion site pain | 5 | 6% | 1 | 1% |
| Feeling cold | 5 | 6% | 0 | |
| Pallor | 4 | 5% | 0 | |
| Dermatitis contact | 4 | 5% | 0 | |
| Syncope | 3 | 4% | 3 | 4% |
| Influenza like illness | 3 | 4% | 1 | 1% |
| Pruritus | 3 | 4% | 1 | 1% |
| Anxiety | 3 | 4% | 0 | |
| Decreased appetite | 3 | 4% | 0 | |
| Chest discomfort | 3 | 4% | 0 | |
| Back pain | 2 | 2% | 2 | 2% |
| Cold sweat | 2 | 2% | 1 | 1% |
| Dizziness postural | 2 | 2% | 1 | 1% |
| Muscle spasms | 2 | 2% | 1 | 1% |
| Presyncope | 2 | 2% | 1 | 1% |
| Vomiting | 2 | 2% | 1 | 1% |
| Arthralgia | 2 | 2% | 1 | 1% |
| Chills | 2 | 2% | 0 | |
| Diarrhea | 2 | 2% | 0 | |
| Discomfort | 2 | 2% | 0 | |
| Dyspnea | 2 | 2% | 0 | |
| Erythema | 2 | 2% | 0 | |
| Hypoesthesia oral | 2 | 2% | 0 | |
| Infusion site | 2 | 2% | 0 | |
| Limb discomfort | 2 | 2% | 0 | |
| Oral discomfort | 2 | 2% | 0 | |
| Catheter site pain | 2 | 2% | 0 | |
| Ecchymosis | 2 | 2% | 0 | |

Other adverse reactions reported to occur following administration of methylene blue class products include the following: *Blood and lymphatic system disorders:* hemolytic anemia, hemolysis, hyperbilirubinemia, methemoglobinemia *Cardiac disorders:* palpitations, tachycardia *Eye disorders:* eye pruritus, ocular hyperemia, vision blurred *Gastrointestinal disorders:* abdominal pain lower, dry mouth, flatulence, glossodynia, tongue eruption *General disorders and administration site conditions:* death, infusion site extravasation, infusion site induration, infusion site pruritus, infusion site swelling, infusion site urticaria, peripheral swelling, thirst *Investigations:* elevated liver enzymes *Musculoskeletal and connective tissue disorders:* myalgia *Renal and urinary disorders:* dysuria *Respiratory, thoracic and mediastinal disorders:* nasal congestion, oropharyngeal pain, rhinorrhea, sneezing *Skin and subcutaneous tissue disorders:* necrotic ulcer, papule, phototoxicity *Vascular disorders:* hypertension *Clinical Studies information is approved for PROVEPHARM SAS's Provayblue® (Methylene blue solution, intravenous). However, due to PROVEPHARM SAS's marketing exclusivity rights, this drug product is not labeled with that information.*

**DRUG INTERACTIONS:** Clinically significant drug interactions with methylene blue are described below: The concomitant use of methylene blue with other drugs that affect the serotonergic neurotransmitter system has resulted in serotonin syndrome. Although the mechanism is not clearly understood, literature reports suggest methylene blue is a potent reversible inhibitor of monoamine oxidase. Avoid concomitant use of methylene blue with medicinal products that enhance serotonergic transmission including antidepressants like SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin and norepinephrine reuptake inhibitors), MAOIs (monoamine oxidase inhibitors), bupropion, buspirone, clomipramine, mirtazapine, linezolid, opioids, and dextromethorphan because of the potential for serious CNS reactions, including potentially fatal serotonin syndrome. If the intravenous use of methylene blue cannot be avoided in patients treated with serotonergic medicinal products, choose the lowest possible dose and observe the patient closely for CNS effects for up to 4 hours after administration *[see Warning and Precautions and Clinical Pharmacology]*.

**USE IN SPECIFIC POPULATIONS:** **Pregnancy:** *Risk Summary:* Methylene blue may cause fetal harm when administered to a pregnant woman. Intra-amniotic injection of pregnant women with a methylene blue class product during the second trimester was associated with neonatal intestinal atresia and fetal death. Methylene blue produced adverse developmental outcomes in rats and rabbits when administered orally during organogenesis at doses at least 32 and 16 times, respectively, the clinical dose of 1 mg/kg *[see Data]*. Advise pregnant women of the potential risk to a fetus. In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies are 2-4% and 15-20%, respectively. Clinical Considerations: *Fetal/neonatal adverse reactions: Intra*-amniotic injection of a methylene blue class product hours to days prior to birth can result hyperbilirubinemia, hemolytic anemia, skin staining, methemoglobinemia, respiratory distress and photosensitivity in the newborn. Following administration of methylene blue to a pregnant woman at term, observe the newborn for these adverse reactions and institute supportive care. Data: *Animal Data:* Methylene blue was administered orally to pregnant rats at doses of 50 to 350 mg/kg/day, during the period of organogenesis. Maternal and embryofetal toxicities were observed at all doses of methylene blue and were most evident at the 200 and 350 mg/kg/day doses. Maternal toxicity consisted of increased spleen weight. Embryo-fetal toxicities included reduced fetal weight, post-implantation loss, edema, and malformations including enlarged lateral ventricles. The dose of 200 mg/kg (1200 mg/m$^2$) in rats is approximately 32 times a clinical dose of 1 mg/kg based on body surface area. Methylene blue was administered orally to pregnant rabbits at doses of 50, 100, or 150 mg/kg/day, during the period of organogenesis. Maternal death was observed at the methylene blue dose of 100 mg/kg. Embryofetal toxicities included spontaneous abortion at all dose levels and a malformation (umbilical hernia) at the 100 and 150 mg/kg/day doses. The dose of 50 mg/kg (600 mg/m$^2$) in rabbits is approximately 16 times a clinical dose of 1 mg/kg based on body surface area. **Lactation:** *Risk Summary:* There is no information regarding the presence of methylene blue in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions including genotoxicity, discontinue breast-feeding during and for up to 8 days after treatment with methylene blue *[see Clinical Pharmacology]*. **Pediatric Use:** The safety and effectiveness of methylene blue have been established in pediatric patients. Use of methylene blue is supported by two retrospective case series that included 2 pediatric patients treated with methylene blue and 12 treated with another methylene blue class product. The case series included pediatric patients in the following age groups: 3 neonates (less than 1 month), 4 infants (1 month up to less than 2 years), 4 children (2 years up to less than 12 years), and 3 adolescents (12 years to less than 17 years). The efficacy outcomes were consistent across pediatric and adult patients in both case series *[see Clinical Studies]*. **Geriatric Use:** The retrospective case series included 3 patients age 65 years and over treated with methylene blue injection (or a bioequivalent formulation) and 5 treated with another methylene blue class product. The efficacy outcomes were consistent across adult and elderly patients in both case series *[see Clinical Studies]*. Methylene blue is known to be substantially excreted by the kidney, so the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, treatment of methemoglobinemia in these patients should use the lowest number of doses needed to achieve a response *[see Dosage and Administration]. Clinical Studies information is approved for PROVEPHARM SAS's Provayblue® (Methylene blue solution, intravenous). However, due to PROVEPHARM SAS's marketing exclusivity rights, this drug product is not labeled with that information.* **Renal Impairment:** Methylene blue concentrations increased in subjects with renal impairment (eGFR 15 to 89 mL/min/1.73m$^2$) significantly *[see Clinical Pharmacology]*. Adjust methylene blue dosage in patients with moderate or severe renal impairment (eGFR 15 to 59 mL/min/1.73 m$^2$) *[see Dosage and Administration]*. No dose adjustment is recommended in patients with mild renal impairment (eGFR 60 - 89 mL/min/1.73 m$^2$). **Hepatic Impairment:** Methylene blue is extensively metabolized in the liver. Monitor patients with any hepatic impairment for toxicities and potential drug interactions for an extended period of time following treatment with methylene blue.

**OVERDOSAGE:** Hypotension, wheezing and reduced oxygenation have been reported in patients who received methylene blue class products in single doses of 3 mg/kg or more. Administration of large intravenous doses (cumulative dose ≥ 7 mg/kg) of a methylene blue class product caused nausea, vomiting, precordial pain, dyspnea, tachypnea, chest tightness, tachycardia, apprehension, tremor, mydriasis, blue staining of the urine, the skin and mucous membranes, abdominal pain, dizziness, paresthesia, headache, confusion, mild methemoglobinemia (up to 7%) and electrocardiogram changes (T-wave flattening or inversion). These effects lasted 2-12 hours following administration. A severe overdosage (single dose of 20 mg/kg or more) of a methylene blue class product caused severe intravascular hemolysis, hyperbilirubinemia and death. In case of overdose of methylene blue, maintain the patient under observation until signs and symptoms have resolved, monitor for cardiopulmonary, hematologic and neurologic toxicities, and institute supportive measures as necessary.

**Call your doctor for medical advice about side effects.**
**You may report side effects to FDA at 1-800-FDA-1088.**

Please address medical inquiries to, MedicalAffairs@zydususa.com or Tel.: 1-877-993-8779.

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Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) is a rare form of ALL that affects approximately 25% of adult ALL patients in the U.S. and is characterized by the presence of an abnormal gene, known as the Philadelphia chromosome. In patients who are Philadelphia chromosome-positive (Ph+), an abnormal chromosome is formed when pieces of chromosomes 9 and 22 switch with each other. This forms a longer chromosome 9 and a shorter chromosome 22, which leads to the development of BCR::ABL1 and is associated with Ph+ ALL.

Iclusig is a kinase inhibitor drug targeting BCR::ABL1, an abnormal tyrosine kinase that is expressed in CML and Ph+ ALL. It was developed using a computational and structure-based drug-design platform specifically designed to inhibit the activity of BCR::ABL1 and its mutations. Iclusig inhibits native BCR::ABL1, as well as all BCR::ABL1 treatment-resistant mutations, including the most resistant T315I mutation, which has been associated with resistance to all other approved TKIs.

The FDA granted Iclusig with Priority Review for this indication, and it was evaluated under the Real-Time Oncology Review (RTOR) program, an FDA initiative designed to expedite the delivery of cancer medicines by allowing components of an application to be reviewed before submission of the complete application.

**Elias Jabbour,** M.D., The University of Texas MD Anderson Cancer Center in Houston (and lead investigator of the clinical drug trial), said: "Ph+ ALL is an extremely aggressive cancer and patients with this disease suffer from poor outcomes. There has long been a need for a potent TKI that can suppress mutation development and elicit deep responses in the frontline. Ponatinib may help address these factors and impact long-term outcomes."

Originally, Iclusig received FDA-approval in November 2016.

### Keytruda® + Chemoradiotherapy For FIGO 2014 Stage III-IVA Cervical Cancer - New Indication

On January 12, Merck & Co., Inc. of Rahway, New Jersey announced the FDA approved a ***new indication*** for Keytruda® (pembrolizumab) Injection for intravenous (IV) use, in combination with chemoradiotherapy for the treatment of patients with FIGO (International Federation of Gynecology and Obstetrics) 2014 Stage III-IVA cervical cancer.

Cervical cancer forms in the cells lining the cervix, which is the lower part of the uterus. While screenings and prevention have resulted in declining cervical cancer rates, the disease continues to affect many people in the U.S. and around the world. Cervical cancer is the fourth most common cancer in women globally. In the U.S., it is estimated there were approximately 13,960 new cases of invasive cervical cancer and about 4,310 deaths from cervical cancer in 2023.

**Bradley Monk,** M.D., Oncologist and Professor of Obstetrics & Gynecology at University of Arizona's College of Medicine and Creighton University School of Medicine at St. Joseph's Hospital & Medical Center both located in Phoenix, said: "This approval of Keytruda plus chemoradiotherapy is welcome news and gives patients with newly diagnosed FIGO 2014 Stage III-IVA cervical cancer, for the first time ever, the option of an anti-PD-1-based regimen to treat their cancer. This Keytruda-based regimen offers a new treatment option for these patients, so the approval has important implications for the way we treat them moving forward."

***Note:*** Keytruda should not be administered to pregnant women, due to possible fetal harm.

### Onivyde® Injection For Metastatic Pancreatic Adenocarcinoma - Expanded Indication

On February 13, Ipsen of Paris, France (with U.S. headquarters in Cambridge, Massachusetts) announced the FDA approval for an ***expanded indication*** of Onivyde® (irinotecan liposome) Injection for intravenous (IV) use—with oxaliplatin, fluorouracil, and leucovorin (NALIRIFOX, a chemotherapy therapy), now also as a first-line treatment in adults living with metastatic pancreatic adenocarcinoma.

Onivyde is administered via intravenous infusion over 90 minutes every two weeks, with recommendations on dosing modifications.

Pancreatic adenocarcinoma (PDAC) is the most common type of cancer that forms in the pancreas, with more than 60,000 people diagnosed in the U.S. each year and nearly 500,000 people globally. Since there are no specific symptoms in the early stages, it is often detected late and after the disease has spread to other parts of the body. Characterized as a complex cancer due to rapid tumor progression, limited genetic targets, and multiple resistance mechanisms.

Metastatic pancreatic adenocarcinoma has a poor prognosis with fewer than 20% of people surviving longer than one year. Overall, pancreatic cancer has the lowest 5-year survival rate of all cancer types globally and in the United States. Weight loss, abdominal pain, and jaundice are the most common symptoms, making PDAC difficult to detect. Despite significant advances in cancer treatments since the 1970s, no treatment options for PDAC significantly extend life.

Onivyde is a cancer medicine that blocks an enzyme called topoisomerase I, which is involved in copying cell DNA needed to make new cells. By blocking the enzyme, cancer cells are prevented from multiplying and eventually die.

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In Onivyde, irinotecan is enclosed in tiny fat particles called 'liposomes,' which accumulate in the tumor and release slowly over time. Onivyde may be prescribed immediately in the U.S. for eligible people living with mPDAC who are treatment naïve or following gemcitabine-based therapy.

**Zev Wainberg,** M.D., Professor of Medicine & Co-Director of the University of California Los Angeles (UCLA) GI Oncology Program, said: "Metastatic pancreatic adenocarcinoma is a difficult disease to manage with very few available treatment options. Given the reality of this aggressive form of cancer and the complexity of the disease, every advance in the treatment landscape represents a meaningful improvement in patient outcomes. The approval of this Onivyde regimen is an important milestone for people living with metastatic pancreatic adenocarcinoma, their families and healthcare providers, with the clinical trial having demonstrated survival benefits versus a current standard of care treatment option."

### Opdivo ® + Cisplatin & Gemcitabine For Metastatic Urothelial Carcinoma - New Dosing Regimen

On March 7, Bristol Myers Squibb of Princeton, New Jersey announced the FDA approved a ***new dosing regimen*** for Opdivo® (nivolumab) Injection for intravenous (IV) use, now also in combination with cisplatin and gemcitabine, for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma, the most common type of bladder cancer.

Bladder cancer is the sixth most common cancer in the U.S., with an estimated 83,190 new cases expected to be diagnosed in 2024. Urothelial carcinoma (UC), which most frequently begins in the cells that line the inside of the bladder, accounts for approximately 90% of bladder cancer cases. In addition to the bladder, urothelial carcinoma can occur in other parts of the urinary tract, including the ureters and renal pelvis. The majority of urothelial carcinomas are diagnosed at an early stage, but approximately 50% of patients who undergo radical surgery will experience disease progression and recurrence, generally within 2 years post-surgery. Approximately 20% to 25% of patients with urothelial carcinoma present with metastatic disease, and treatment challenges have historically persisted in the first- and second-line settings, in part due to limited therapeutic options.

**Guru P. Sonpavde,** M.D., Medical Director of Genitourinary Oncology and the Phase I Clinical Research Unit and Christopher K. Glanz Chair for Bladder Cancer Research at the AdventHealth Cancer Institute, Orlando, Florida. "This approval marks an important advancement in a historically difficult-to-treat setting, where there has been a need for new and differentiated first-line approaches that may offer patients a chance to live longer. Based on outcomes and the safety profile seen in the clinical trial, the approval of Opdivo in combination with cisplatin and gemcitabine has the potential to change how metastatic or unresectable UC is treated for certain patients and offers them new hope."

The FDA granted Opdivo with Priority Review, as well as being approved under their Real-Time Oncology Review (RTOR) pilot program, which aims to ensure that safe and effective treatments are available to patients as early as possible. The review was also conducted under the FDA's Project Orbis initiative, which enables concurrent review by the health authorities in several other countries.

### Praluent® Injection For Pediatric Genetic High Cholesterol - Extended Indication

On March 11, Regeneron Pharmaceuticals, Inc. of Tarrytown, New York announced the FDA approved an ***extended indication*** for Praluent® (alirocumab) Injection for subcutaneous use, now also for pediatric patients aged 8 and older with heterozygous familial hypercholesterolemia, as an adjunct to diet and other low-density lipoprotein cholesterol (LDL-C) lowering therapies.

Familial hypercholesterolemia (FH) is an inherited condition caused by mutations in one of several genes that control how the body processes cholesterol, which can lead to very high levels of LDL-C (bad cholesterol). FH can come in two forms. First is as heterozygous familial hypercholesterolemia (HeFH), which develops when one mutated gene is inherited from one parent. Second is as homozygous familial hypercholesterolemia (HoFH), which develops when a mutated gene is inherited from both parents. Praluent is approved to treat HeFH in both children and adults, as well as for the treatment of adults with HoFH.

Praluent inhibits the binding of PCSK9 to the LDL receptor and thereby increases the number of available LDL receptors on the surface of liver cells to clear LDL, which lowers LDL-C levels in the blood.

**Mary P. McGowan,** M.D., Chief Medical Officer of the Family Heart Foundation of Fernandina Beach, Florida, said: "Many children with HeFH are able to substantially improve their LDL-C (bad cholesterol) with currently available therapies. But for those children whose LDL-C remains dangerously high, this approval is an important milestone as it gives these children and their families an additional option to help reduce and manage their LDL-C levels much earlier in their lives."

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Praluent was developed by Regeneron and Sanofi under a global collaboration agreement and invented by Regeneron using the company's proprietary VelocImmune® technology that yields optimized fully-human monoclonal antibodies.

**Rybrevant® + Chemotherapy For Non-Small Cell Lung Cancer With EGFR Exon 20 Insertion Mutations - New Dosing Regimen**

On March 1, the Janssen Pharmaceutical Companies of Johnson & Johnson of Horsham, Pennsylvania announced that the FDA has approved a ***new dosing regimen*** for Rybrevant® (amivantamab-vmjw) Injection for intravenous (IV) use, now also in combination with chemotherapy (carboplatin-pemetrexed) for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test.

Worldwide, lung cancer is one of the most common cancers, with non-small cell lung cancer (NSCLC) making up 80% to 85% of all lung cancer cases. The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma, and large cell carcinoma. Among the most common driver mutations in NSCLC are alterations in epidermal growth factor receptor (EGFR), which is a receptor tyrosine kinase controlling cell growth and division. EGFR mutations are present in 10% to 15% of Western patients with NSCLC with adenocarcinoma histology and occur in 40% to 50% of Asian patients. The 5-year survival rate for all people with advanced NSCLC and EGFR mutations treated with EGFR TKIs is less than 20%. Patients with EGFR ex19del or L858R mutations have a real-world 5-year survival rate of 19%.

**Joshua K. Sabari,** M.D., Oncologist with the New York University Langone's Perlmutter Cancer Center (and the drug's study investigator), said: "When aiming for the best possible treatment outcomes, a targeted approach should be used in the first line for patients with EGFR exon 20 insertion mutations, as this is a commonly applied practice for patients with NSCLC harboring other molecular driver alterations. The results observed in the clinical drug study showed significant improvement in progression-free survival, supporting the use of this regimen as the potential standard-of-care in the first-line treatment of these patients."

**Spevigo® Injection For Generalized Pustular Psoriasis In Patients Aged 12 & Older - Expanded Indication**

On March 19, Boehringer Ingelheim Pharmaceuticals, Inc. of Ridgefield, Connecticut announced the FDA approved an ***expanded indication*** for Spevigo® (spesolimab-sbzo) Injection for intravenous (IV) use, now also for the treatment of generalized pustular psoriasis in adults and pediatric patients aged 12 and above weighing 40kg.

Distinct from plaque psoriasis, generalized pustular psoriasis (GPP) is a rare, chronic, heterogenous, inflammatory neutrophilic disease associated with painful skin manifestations and systemic symptoms, such as fever, pain, and fatigue. GPP varies widely in people with the condition, since symptoms present on a continuum, which means that it can present in either a persistent or a relapsing course. GPP often requires emergency care and can lead to life-threatening complications, such as multi-organ failure and sepsis. GPP greatly impacts a patient's quality of life, and may cause fear and anxiety over the disease course, as well as long-term impacts on quality of life related to work/school, emotional health, social activities, and finances.

Spevigo is a novel, humanized, selective antibody that specifically blocks the activation of the IL-36R, a signaling pathway within the immune system shown to be involved in the pathogenesis of several autoinflammatory diseases, including GPP. It is the first targeted therapy for the treatment of GPP and has been evaluated in the largest clinical program specifically for the treatment of patients with GPP.

**Carinne Brouillon,** Member of the Board of Managing Directors & Head of Human Pharma at Boehringer Ingelheim, said: "Spevigo's new approvals constitute a fundamental change for people living with GPP, addressing their huge need for acute and chronic treatment. Experiencing GPP can be mentally and physically devastating, leaving those affected with uncertainty and fear of the next episode. Therefore, expanding the treatment of GPP is a critical step towards addressing patients' needs."

**Tagrisso® Tablets + Chemotherapy For EGFR-Mutated Advanced Lung Cancer**

On February 16, AstraZeneca of Wilmington, Delaware announced the FDA approved an ***expanded indication*** for Tagrisso® (osimertinib) Tablets, now also with the addition of chemotherapy for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor-mutated non-small cell lung cancer.

Each year in the U.S., there are over 200,000 people diagnosed with lung cancer, and 80% to 85% of these patients are diagnosed with non-small cell lung cancer (NSCLC), the most common form of lung cancer. Approximately 70% of people are diagnosed with advanced NSCLC. Additionally, about 15% of NSCLC patients in the U.S. have an epidermal growth factor receptor (EGFR) mutation.

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**Dave Fredrickson,** Executive VP of the Oncology Business Unit at AstraZeneca, said: "This important new treatment option can delay disease progression by nearly nine additional months, establishing a new benchmark with the longest reported progression-free survival benefit in the 1st-line advanced setting. This approval reinforces TAGRISSO as the backbone of EGFR-mutated lung cancer treatment either as monotherapy or in combination with chemotherapy. This news is especially important for those with a poorer prognosis, including patients whose cancer has spread to the brain and those with L858R mutations."

### Tecvayli® Injection For Relapsed Or Refractory Multiple Myeloma - New Biweekly Dosing Regimen

On February 20, Johnson & Johnson, Inc. of Horsham, Pennsylvania announced the FDA approval of the supplemental Biologics License Application (sBLA) for Tecvayli® (teclistamab-cqyv) Injection for a ***new reduced dosing*** frequency of 1.5mg/kg every 2 weeks, in patients with relapsed or refractory multiple myeloma who have achieved and maintained a complete response or better for a minimum of 6 months.

There is a continued unmet need for patients with multiple myeloma and this approval allows increased flexibility in dosing schedule for appropriate patients with a weight-based regimen.

Tecvayli, which is administered subcutaneously, was the first bispecific antibody targeting B-cell maturation antigen (BCMA) on multiple myeloma cells and CD3 on T-cells to activate an immune response.

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow. In multiple myeloma, these plasma cells proliferate and spread rapidly and replace normal cells in the bone marrow with tumors. Multiple myeloma is the third most common blood cancer worldwide and remains an incurable disease. In 2024, it was estimated that more than 35,000 people will be diagnosed with multiple myeloma in the U.S. and more than 12,000 people would die from the disease. People living with multiple myeloma have a 5-year survival rate of 59.8%. While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, and kidney problems or infections.

Tecvayli is a first-in-class, bispecific T-cell engager antibody therapy that uses innovative science to activate the immune system by binding to the CD3 receptor expressed on the surface of T-cells and to the B-cell maturation antigen (BCMA) expressed on the surface of multiple myeloma cells and some healthy B-lineage cells.

**Rachel Kobos,** M.D., VP of Oncology Research & Development at Johnson & Johnson Innovative Medicine, said: "Tecvayli is the only BCMA-targeted immune-based therapy with weight-based dosing. This approval of biweekly dosing for eligible patients will further enable clinicians to meet the individual needs of patients who may want flexibility in their dosing schedules. As the first bispecific approved for the treatment of multiple myeloma, combined with the longest in-market experience by physicians. Tecvayli is another example of our commitment to pioneering cutting-edge research to help improve outcomes for patients with multiple myeloma."

Tecvayli originally received FDA-approval in October 2022 as a ready-to-use antibody drug that is administered as a subcutaneous injection treatment for adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody.

### Ultomiris® For Neuromyelitis Optica Spectrum Disorder - New Indication

On March 25, AstraZeneca USA of Wilmington, Delaware and its subsidiary, Alexion, AstraZeneca Rare Disease of Boston, Massachusetts jointly announced the FDA approved a ***new indication*** for Ultomiris® (ravulizumab-cwvz) Injection for intravenous (IV) use, now also as the ***first and only*** long-acting C5 complement inhibitor for the treatment of adult patients with anti-aquaporin-4 antibody-positive (Ab+) neuromyelitis optica spectrum disorder.

Neuromyelitis optica spectrum disorder (NMOSD) is a rare and debilitating autoimmune disease that affects the central nervous system (CNS), including the spine and optic nerves. Most people living with NMOSD experience unpredictable relapses, characterized by a new onset of neurologic symptoms or worsening of existing neurologic symptoms, which tend to be severe and recurrent and may result in permanent disability. The diagnosed prevalence of adults with NMOSD in the U.S. is estimated at about 6,000.

NMOSD most commonly affects women and begins in the mid-30s. Men and children may also develop NMOSD, but it is even more rare. People with NMOSD may experience vision problems, intense pain, loss of bladder/bowel function, abnormal skin sensations (e.g., tingling, prickling, or sensitivity to heat/cold), and impact on coordination and/or movement. Most people living with

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NMOSD experience unpredictable relapses, also known as attacks. Each relapse can result in cumulative disability including vision loss, paralysis, and sometimes premature death. NMOSD is a distinct disease from other CNS diseases, including multiple sclerosis. The journey to diagnosis can be long, with the disease sometimes misdiagnosed.

Ultomiris, the first and only long-acting C5 complement inhibitor, provides immediate, complete, and sustained complement inhibition. The medication works by inhibiting the C5 protein in the terminal complement cascade, a part of the body's immune system. When activated in an uncontrolled manner, the complement cascade over-responds, leading the body to attack its own healthy cells. Ultomiris is administered intravenously every 8 weeks in adult patients, following a loading dose.

**Sean J. Pittock,** M.D., Director of Mayo Clinic's Center for Multiple Sclerosis & Autoimmune Neurology and of Mayo's Neuroimmunology Laboratory in Rochester, Minnesota (and lead primary investigator in the clinical trial), said: "C5 inhibition has been proven to offer efficacy in reducing the risk of NMOSD relapses by blocking the complement system, a part of the immune system, from attacking healthy cells in the spinal cord, optic nerve, and brain. With this new approval, patients now have the option of a long-acting C5 inhibitor treatment that showed zero relapses in its pivotal clinical trial, supporting the primary goal of relapse prevention in treating NMOSD."

### Wegovy® Injection For CVD Risk Reduction In Overweight Adults With Known Heart Disease

On March 8, Novo Nordisk, Inc. of Plainsboro, New Jersey announced the FDA approved a ***new indication*** on Wegovy® (semaglutide) Injection for subcutaneous use, now also indicated to reduce the risk of major cardiovascular events in adults with known heart disease and with either obesity or overweight along with a reduced calorie diet and increased physical activity.

Wegovy is the ***first-and-only*** medicine indicated for ***both*** reduction of the risk of major adverse cardiovascular events (MACE) such as death, heart attack, or stroke and for long-term weight management.

Wegovy is administered via a pre-filled, single-dose pen that delivers doses of 0.25mg, 0.5mg, 1mg, 1.7mg, or 2.4mg. It is a once weekly subcutaneous injection (in the abdomen, thigh or upper arm) on the same day each week, at any time of day, with or without meals. Dosing should be initiated at 0.25mg once weekly for 4 weeks. Then follow the dosage escalation schedule, titrating every 4 weeks to achieve the maintenance dosage. The recommended maintenance dosage of Wegovy is 2.4mg, or 1.7mg once weekly as another option.

The prevalence of overweight and obesity is a public health issue that has severe cost implications to healthcare systems. In the U.S., about 42% of adults live with obesity.

Between 1999 and 2020 in the U.S., obesity-related cardiovascular disease deaths tripled, according to the American Heart Association (AHA). In fact, more than 1 in 3 U.S. adults live with obesity, one of the leading risk factors contributing to heart disease and stroke.

Obesity is a serious chronic, progressive, and misunderstood disease that requires long-term management. One key misunderstanding is it is a disease of lack of willpower, when in fact there is underlying biology that may impede people with obesity from losing weight and keeping it off. Obesity is influenced by a variety of factors, including genetics, social determinants of health, and the environment.

Cardiovascular disease (CVD) is the leading cause of death in the United States. More than 800,000 people die from CVD each year in the U.S. (1 in every 3 deaths) with about 160,000 of these deaths occurring in people younger than 65 years. Obesity increases the risk of developing high blood pressure or high blood cholesterol, both contributing factors to CVD. Residual risk for another cardiovascular event in people with obesity and known heart disease remains despite treatment of known cardiovascular risk factors such as high blood pressure and high cholesterol according to standard of care treatments.

The FDA granted Wegovy with Priority Review designation for this indication.

**John Sharretts,** M.D., Director of the Division of Diabetes, Lipid Disorders & Obesity in the FDA's Center for Drug Evaluation & Research, said: "Wegovy is now the first weight loss medication to also be approved to help prevent life-threatening cardiovascular events in adults with cardiovascular disease and either obesity or overweight. This patient population has a higher risk of cardiovascular death, heart attack, and stroke. Providing a treatment option that is proven to lower this cardiovascular risk is a major advance for public health."

### Xhance® Nasal Spray For Chronic Rhinosinustis (No Polyps)- New Indication

On March 15, Optinose, Inc. of Yardley, Pennsylvania announced the FDA approval of a ***new indication*** for Xhance® (fluticasone propionate) Nasal Spray, now also for the treatment of chronic rhinosinusitis without nasal polyps, in patients 18 years of age and older.

# New Drugs/Indications

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Chronic sinusitis (CRS, also called chronic rhinosinusitis) is one of the most common chronic diseases, affecting approximately 30 million adults in the United States. Research shows that the disease impairs quality of life to a similar degree as other serious chronic conditions, such as chronic obstructive pulmonary disease, sciatica, or migraine. It is also one of the most common diagnoses in adult outpatient medicine. CRS is diagnosed in approximately 10 million outpatient visits, of which approximately 70% result in antibiotic prescriptions, and leads to more than 600,000 surgeries annually.

Although there are FDA-approved medications to treat nasal polyps, including Xhance, no medication had ever been approved for the more than two-thirds of chronic sinusitis patients who do not have nasal polyps, until now.

Xhance is a drug-device combination product that uses the Exhalation Delivery System™ (EDS), which is designed to deliver a topical steroid to the high and deep regions of the nasal cavity where sinuses ventilate and drain.

**Ramy Mahmoud,** M.D., MPH, CEO of Optinoses, said: "People who don't suffer from chronic sinusitis may not appreciate how burdensome the condition can be. More than 80% of patients with chronic sinusitis report frustration with symptom relief when using a standard-delivery nasal steroid sprays, and patients commonly use multiple unproven over the counter medications in an effort to find symptom relief. Although chronic sinusitis is one of the most common diagnoses in outpatient physician visits, and surgery is available, there has never been a prescription medication approved by the FDA as safe and effective to treat the millions of patients without nasal polyps suffering from this debilitating disease. We are thrilled to now be able to offer new hope to these patients and believe Xhance has the potential to become part of the standard of care for the treatment of chronic sinusitis."

### Xolair® Injection - First & Only Medicine To Help Reduce Allergic Reactions

On February 16, Genentech, Inc. (a member of the Roche Group) of South San Francisco, California and Novartis Pharmaceuticals Corporation of East Hanover, New Jersey jointly announced the FDA approved Xolair® (omalizumab) Injection for subcutaneous use, indicated for the reduction of allergic reactions including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with an Immunoglobulin E-mediated food allergy.

Product is available in the following presentations and strengths.

- **Autoinjector** in a prefilled single-dose autoinjector: 75mg/0.5mL, 150mg/mL, and 300mg/2mL.
- **Lyophilized Powder** in a single-dose vial for reconstitution: 150mg.
- **Solution** in a single-dose prefilled syringe: 75mg/0.5mL, 150mg/mL, and 300mg/2mL.

Xolair is the ***first and only*** FDA-approved medicine to reduce allergic reactions for more than one type of food, after having an accidental exposure.

The recommended Xolair dosage for treatment of food allergy is 75mg to 600mg once every 2 or 4 weeks. Its dose and dosing frequency is determined by total serum IgE level and body weight. Injections can either be given by a healthcare provider in a healthcare setting, or at home through self-injection (after initiating in a healthcare setting to start).

According to the U.S. Centers for Disease Control & Prevention (CDC), approximately 6% of people in the United States in 2021 (and increasing each year) had a food allergy and reaction after exposure to those foods. About 3.4 million children and 13.6 million adults in the U.S. have been further diagnosed with IgE-mediated food allergies (based on estimates for 2024). There is currently no cure for food allergies and its prevalence has been on the rise for the past 20 years.

IgE-mediated food allergies are the most common type of food allergy and are typically characterized by the rapid onset of symptoms following exposure to certain foods. There are 160 different foods that cause IgE-mediated food allergy. Allergic reactions can range from mild to moderate (including hives and swelling) to severe and life-threatening (such as anaphylaxis). More than 40% of children and more than half of adults with food allergies have experienced a severe reaction at least once.

Hospital emergency rooms (ERs) in the U.S. currently report they treat an estimated 30,000 food-related anaphylaxis events each year. Current treatment requires strict avoidance of the foods the patient is allergic to and prompt administration of epinephrine to treat anaphylaxis should accidental exposures occur.

Xolair is designed to target and block Immunoglobulin E (IgE), an underlying driver of food allergy reactions. By reducing free IgE, down-regulating high-affinity IgE receptors and limiting mast cell degranulation, the drug minimizes the release of mediators throughout the allergic inflammatory cascade.

The FDA granted Xolair with Priority Review as well as a Breakthrough Therapy designation for this indication.

*Continued on Page 42*

PAI Pharma

# CETIRIZINE HYDROCHLORIDE ORAL SOLUTION, USP

## 1 mg/mL


### PRODUCT OVERVIEW:

- **Dye-Free**
- **Rx or OTC:** Rx
- **Flavor:** Unflavored
- **Storage & Handling:** Store at 20˚ to 25˚C (68˚ to 77˚F)

| NDC | Product Description | Cardinal | Cencora | McKesson | Morris Dickson |
|---|---|---|---|---|---|
| 00121-0874-16 | Cetirizine Hydrochloride Oral Solution 480 mL bottle 1 mg/mL Rx 12/cs | 5905476 | 10286990 | 2899813 | 334300 |
| 00121-0874-04 | Cetirizine Hydrochloride Oral Solution 120 mL bottle 1 mg/mL Rx 12/cs | 5929211 | 10289925 | 2965119 | TBD |

| Product Description | GTIN Product Barcode | GTIN Case Barcode |
|---|---|---|
| Cetirizine Hydrochloride Oral Solution 480 mL bottle 1 mg/mL Rx 12/cs | (01) 00301210874161 | (01) 20301210874165 |
| Cetirizine Hydrochloride Oral Solution 120 mL bottle 1 mg/mL Rx 12/cs | (01) 00301210874048 | (01) 20301210874042 |

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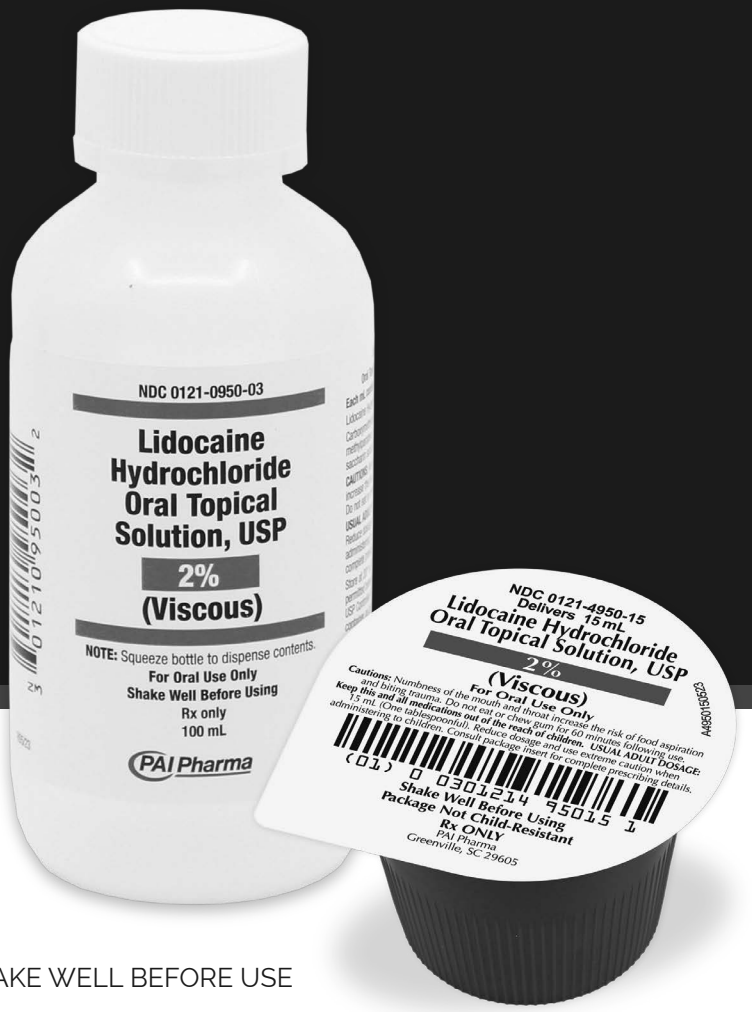
# LIDOCAINE VISCOUS 2%

## Lidocaine Hydrochloride Oral Topical Solution, USP




### PRODUCT OVERVIEW:

- **Alcohol, Dye, and Sugar-Free**
- **Rx or OTC:** Rx
- **Flavor:** Cherry
- **Storage & Handling:** Store at 20° to 25°C (68° to 77°F). SHAKE WELL BEFORE USE

| NDC | Product Description | Cardinal | Cencora | McKesson | Morris Dickson |
|---|---|---|---|---|---|
| 00121-4950-40 | Lidocaine Viscous 2%<br>15 mL cups Rx 40/cs | 5905096 | 10287060 | 2909000 | 356089 |
| 00121-0950-03 | Lidocaine Viscous 2%<br>100 mL bottles Rx 12/cs | 5929229 | 10289968 | 2965127 | TBD |

| Product Description | GTIN Product Barcode | GTIN Case Barcode |
|---|---|---|
| Lidocaine Viscous 2%<br>15 mL cups Rx 40/cs | (01) 00301214950151 | (01) 20301214950407 |
| Lidocaine Viscous 2%<br>100 mL bottles Rx 12/cs | (01) 00301210972515 | (01) 20301210950036 |

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# Biosimilar Drug Approvals & News

**Cimerli® Ophthalmic Injection (Lucentis® Biosimilar) - Sandoz Completes Acquisition From Coherus**

On March 4, Sandoz AG of Basel, Switzerland (with U.S. headquarters in Princeton, New Jersey) announced they have completed the acquisition of the Cimerli® (ranibizumab-eqrn) Injection ophthalmology franchise and its supporting commercial infrastructure, from Coherus BioSciences, Inc. of Redwood City, California.

This product is an FDA-approved biosimilar to Lucentis® (ranibizumab) by Genentech USA, Inc.

Cimerli Solution for Injection 0.3mg (6mg/mL) and 0.5mg (10mg/mL) is indicated for the treatment of multiple retinal diseases including wet age-related macular degeneration, diabetic macular edema, macular edema following retinal vein occlusion, myopic choroidal neovascularization, and diabetic retinopathy.

**Jubbonti® Injection - First & Only Interchangeable Biosimilar To Prolia®**

On March 5, Sandoz Inc. of Princeton, New Jersey announced the FDA approval of Jubbonti® (denosumab-bbdz) Injection 60mg/1mL, which is indicated to treat all indications of its referenced biosimilar medicine.

This product is the ***first and only*** FDA-approved interchangeable biosimilar to Prolia® (denosumab) Injection by Amgen, Inc.

Jubbonti has the same dosage form, route of administration, dosing regimen and presentation as its respective reference medicine; and is approved as interchangeable to the reference medicine for all indications.

It is indicated for the following: To treat postmenopausal women with osteoporosis at high risk for fracture; to increase bone mass in men with osteoporosis at high risk for fracture; to treat glucocorticoid-induced osteoporosis in men and women at high risk for fracture; to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; and to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. Also note in pediatric patients, it is only recommended for skeletally mature adolescents with giant cell tumor of bone.

Osteoporosis is a bone disease that develops when bone mineral density and bone mass decrease or when bone strength and structure change. People living with osteoporosis typically

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# New Drugs/Indications

*Continued from Page 39*

**Kelly Stone,** M.D., Ph.D., Associate Director of the Division of Pulmonology, Allergy & Critical Care in the FDA's Center for Drug Evaluation & Research, said: "This newly approved use for Xolair will provide a treatment option to reduce the risk of harmful allergic reactions among certain patients with IgE-mediated food allergies. While it will not eliminate food allergies or allow patients to consume food allergens freely, its repeated use will help reduce the health impact if accidental exposure occurs."

**Zynrelef® Solution For Additional Orthopedic & Soft Tissue Procedures - Expanded Indication**

On January 23, Heron Therapeutics, Inc. of San Diego, California announced the FDA approval of an ***expanded indication*** of their supplemental New Drug Application (sNDA) for Zynrelef® (bupivacaine/meloxicam) Extended-Release Solution, now also for soft tissue and orthopedic surgical procedures including foot and ankle, and other procedures in which direct exposure to articular cartilage is avoided.

Zynrelef was previously approved for foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures in adults. This expanded indication will now cover an estimated 13 million procedures annually, an estimated increase of 86% over prior indicated procedures.

Zynrelef is the first and only dual-acting local anesthetic that delivers a fixed-dose combination of the local anesthetic bupivacaine and a low dose of nonsteroidal anti-inflammatory drug meloxicam. It is the first and only extended-release local anesthetic to demonstrate in Phase 3 clinical studies that it significantly reduced pain as well as significantly increased the proportion of patients not requiring opioids through the first 72 hours following surgery when compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control.

**Alexander Sah,** M.D., Orthopedic Surgeon at Sah Orthopaedic Associates of Fremont, California, said: "Patients undergoing orthopedic procedures often experience severe pain slowing down their recovery time and potentially leading to other complications. Reducing patients' pain within the first three days is critical for patient satisfaction, and having a product like Zynrelef now available for additional orthopedic procedures is a great benefit. Zynrelef helps patients recover fully, be discharged sooner, and have significantly less pain, with little to no opioid use."

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# Outstanding Buyer Nominee - Aleshia Chick

***What is your name (as nominee), job title, facility name, and location?*** **Aleshia Chick**, Pharmacy Buyer, Duncan Regional Hospital (DRH Health System), Duncan, Oklahoma.

***Are you certified, licensed, and/or registered, as a Phar-macy Technician in your state?*** I am a registered technician in Oklahoma, but not nationally certified.

***Are you a current NPPA member, and will be current through this August?*** Yes, I am a new NPPA member, as of April 2024.

***How many beds does your facility have, and what type of facility is it?*** We are a 99-bed rural hospital in Southwest Oklahoma, with 16 clinics. We also operate a 16-bed critical access hospital, a busy 340B hospital, and a hospital-based outpatient infusion center.

***Approximately how many dollars per year of pharmaceutica related expenditures do you purchase or supervise the purchasing of at your facility?*** $5.9 million.

***What is the average dollar amount of pharmacy inventory you control each year?*** Approximately $800,000.

***What is your or your Pharmacy Department's current Inventory "Turns"?*** 7.4.

***How long have you been a Pharmacy Buyer?*** 6 years.

***What are your primary job responsibilities as a Pharmacy Buyer and otherwise?***

- Purchasing cost savings.
- Overseeing clinic purchases.
- Shortage communication.
- Managing critical access inventory.
- Inventory control.

***What is unique or challenging about your facility?*** We are a rural independent organization with 2 hospitals and 18 clinics. 340B compliance and optimization. Keeping inventory low but anticipating drug shortages.

***Additional comments by Ms. Berryhill:*** Being in a rural setting, we provide many of the same services as metro hospitals, however, our staffing is less. Thus, we wear many hats.

***List any accomplishments or projects you may have instituted that have either saved money for your department/facility, or helped to make your job or the department/facility run more efficiently.*** Implementing programs to check contract pricing and identify cost savings opportunities.

***Additional comments by Ms. Berryhill:*** Specifically, in the past few years we've implemented CostCheck™ by Bluesight, a program that gathers our purchases and compares it to contracts to enable us to find incorrectly billed contract purchases. We also began purchasing the drug contrast agents for our Radiology Department, which has now saved 3.4% on those costs.

***How has your job changed over the years?*** More responsibilities, more challenges. More opportunities to learn and grow to be the best buyer I can be.

***Additional comments by Ms. Berryhill:*** In our hospital system, Aleshia is taking a larger role to help departments outside of pharmacy, to get drugs that are in shortage or to save money.

***What do you like about your job?*** The challenges and learning experiences.

***What do you dislike about your job?*** The sense of wondering if I am doing enough for my facility.

***What advice do you have for drug company vendor representatives?*** An email is always greatly appreciated.

***Additional comments by Ms. Berryhill:*** Please don't just show up in the department unannounced, and also know that even unscheduled phone calls are difficult because it means we need to stop what we're handling or focusing on at the time. Send an email first and make an appointment if needed.

***What specific challenges do you face with your job?*** Drug shortages and keeping up with the latest and greatest opportunities.

***How has your NPPA membership helped in your job and/or personally?*** Being new, I am looking forward to networking and having peers to contact and share solutions with.

***Have you ever attended an NPPA Conference?*** I've never attended an NPPA Conference in the past, since I only recently heard about this great opportunity for the first time.

***If you were one of the top-2 placing awardees for this program, would you be able to attend the upcoming NPPA Conference?*** Yes. I am already registered to attend this year. As well as 2 of my coworkers, who are also speaking on the educational program, for a lecture on "Pandemic Effects & Repercussions In Hospital Pharmacies."

***Do you belong to any other professional organizations besides NPPA?*** Not currently.

***List any other qualifications you may have for this award, such as being recognized by your facility, having an article published, organizing buyer meetings, public speaking, doing volunteer work, etc.*** Not currently.

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# Biosimilar Drug Approvals & News

*Continued from Page 42*

do not have symptoms and might not know they have the disease until they experience a fracture. More than 10 million U.S. adults aged 50 and over live with osteoporosis, a major cause of fractures in postmenopausal women and in older men. Half of all women over the age of 50 will experience an osteoporotic fracture during their lifetime.

This approval is also accompanied by a Jubbonti Risk Evaluation & Mitigation Strategy (REMS) program, which is designed to inform prescribers and patients about the risk of severe hypocalcemia associated with Jubbonti in patients with advanced chronic kidney disease, including dialysis-dependent patients.

***Also note:*** Advise females of reproductive potential of potential risk to the fetus and to use effective contraception during treatment and for at least 5 months after the last dose. Prior to initiating Jubbonti in patients with advanced chronic kidney disease, evaluate for the presence of chronic kidney disease-mineral bone disorder (CKD-MBD), since treatment in these patients should be supervised by a healthcare provider with expertise in its diagnosis and management.

### Simlandi® Injection - First Interchangeable High-Concentration, Citrate-Free (Humira® Biosimilar)

On February 23, Alvotech SA of Reykjavik, Iceland (with U.S. headquarters Alvotech USA Inc. in Leesburg, Virginia) and Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey jointly announced the FDA approval of Simlandi® (adalimumab-ryvk) Injection for subcutaneous use.

This product is an FDA-approved interchangeable biosimilar to Humira® (adalimumab) by AbbVie, Inc. It is indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, adult psoriatic arthritis, adult ankylosing spondylitis, Crohn's disease, adult ulcerative colitis, adult plaque psoriasis, adult hidradenitis suppurativa, and adult uveitis.

Simlandi is ***the first*** high-concentration, citrate-free biosimilar to Humira that has been granted interchangeability status by the FDA and will qualify for interchangeable exclusivity for the 40mg/0.4mL injection. While both low-concentration and high-concentration strength biosimilars of Humira are marketed in the U.S. today, nearly 88% of U.S. prescriptions for adalimumab are for the high-concentration presentation.

An interchangeable biosimilar may be substituted at the pharmacy without consulting the prescriber, much like generic drugs are routinely substituted for brand name drugs. As the only interchangeable adalimumab biosimilar with the high-concentration formulation, Simlandi can be substituted for Humira at the pharmacy level, subject to state pharmacy laws.

In 2023, Humira was one of the highest-grossing pharmaceutical products in the world, with sales in the U.S. of nearly $12.2 billion, according to IQVIA.

Teva is Alvotech's strategic partner for the exclusive commercialization of Simlandi in the United States. Both Alvotech and Teva expect to launch Simlandi in the U.S. imminently with the interchangeability designation.

**Robert Wessman,** Chairman & CEO of Alvotech, said: "We strongly believe that biosimilars are important in addressing inflationary pressures in the healthcare system across all markets, especially in the U.S. where biologics represent well over 40% of all pharmaceutical spending. An interchangeable citrate-free, high concentration biosimilar, adalimumab has the potential to change the market dynamics in a rapidly evolving environment for biosimilars in the United States."

### Tofidence™ Injection - Biosimilar To Actemra®

On September 29, 2023, Biogen Inc. of Cambridge, Massachusetts announced the FDA approved Tofidence™ (tocilizumab-bavi) Injection for intravenous (IV) use.

This product is an FDA-approved interchangeable biosimilar to Actemra® (tocilizumab) Injection by Genentech, Inc. of South San Francisco, California.

Tofidence is indicated for the treatment of moderately to severely active rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis. It is also the first tocilizumab biosimilar approved in the United States.

**Ian Henshaw,** Global Head of Biosimilars at Biogen, said: "The approval of Tofidence in the U.S. marks another positive step toward helping more people with chronic autoimmune conditions gain access to leading therapies. With the increasing numbers of approved biosimilars, we expect increased savings and sustainability for healthcare systems and an increase in physician choice and patient access to biologics."

### Tyenne® Injection - First For Both IV Or SQ Use (Actemra® Biosimilar)

On March 7, Fresenius Kabi USA LLC of Lake Zurich, Illinois announced the FDA has granted approval of Tyenne® (tocilizumab-aazg) Injection, for ***either*** intravenous (IV) or subcutaneous (SQ) use.

This is now the first approved tocilizumab biosimilar in both of these formulations.

*Continued on Page 46*

# Desmopressin Acetate

## INJECTION, USP

3 39822 62002 9

Strength/Dosage & Carton Size

**4 mcg/mL**
**x 10 vials**

NDC Number

| | |
|---|---|
| 10 Digit | 39822-6200-2 |
| 11 Digit | 39822-6200-02 |

Wholesale Pick Numbers

| | |
|---|---|
| Cencora (ABC) | 10287440 |
| Cardinal | 5909627 |
| McKesson | 2917235 |
| Morris Dickson | 358655 |

3 39822 62501 7

Strength/Dosage & Carton Size

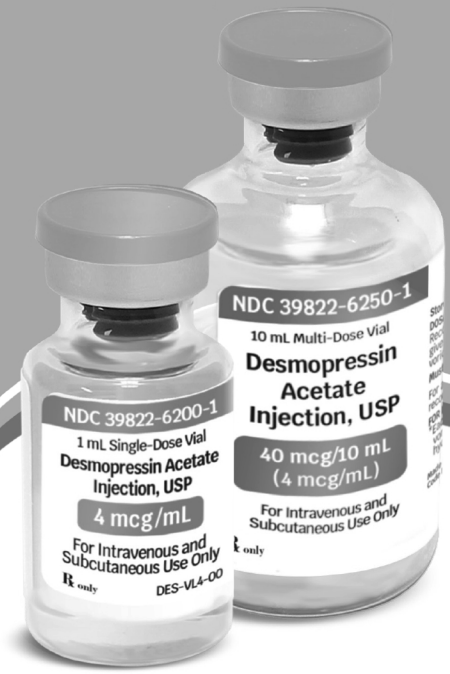
**40 mcg/10mL**
**(4 mcg/mL) x 1 vial**

NDC Number

| | |
|---|---|
| 10 Digit | 39822-6250-1 |
| 11 Digit | 39822-6250-01 |

Wholesale Pick Numbers

| | |
|---|---|
| Cencora (ABC) | 10287369 |
| Cardinal | 5908363 |
| McKesson | 2917243 |
| Morris Dickson | 358713 |

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# Legal Product News

**Ingrezza® Litigation Settled**

On November 13, 2023, Neurocrine Biosciences, Inc. of San Diego, California announced it has resolved all patent litigation related to lawsuits resulting from Abbreviated New Drug Applications (ANDAs) brought by companies seeking approval to market a generic version of Ingrezza® (valbenazine) Capsules prior to the expiration of applicable Neurocrine patents.

As part of the resolution of these lawsuits, four companies have the right to sell generic versions of Ingrezza in the United States beginning March 1, 2038, or earlier under certain customary circumstances.

**Nuplazid® Patent Litigation Ruling**

On December 13, 2023, Acadia Pharmaceuticals Inc. of San Diego, California announced they were granted summary judgment by the U.S. District Court of Delaware confirming validity of the Nuplazid® (pimavanserin) patent (on the drug's composition of matter), and has ruled in favor of Acadia on all grounds, thus concluding the litigation.

The ruling came in Acadia's litigation against MSN Laboratories Ltd., their subsidiary MSN Pharmaceuticals, Inc., and other ANDA filers.

The patent protects the main matter composition patent of Nuplazid into year 2030. Acadia markets two forms of Nuplazid—a 34mg Capsule and a 10mg Tablet. In addition to the matter patent, Acadia also holds an issued method of use patent that protects the 10mg tablet further, to year 2037; and multiple issued formulation patents that protect the 34mg capsule into year 2038.

**Talicia® Granted 5-Year Exclusivity**

On November 27, 2023, RedHill Biopharma, Ltd. of Raleigh, North Carolina announced the FDA has granted 5 years of market exclusivity for Talicia® (amoxicillin/omeprazole magnesium/rifabutin) Delayed-Release Capsules, under the Generating Antibiotic Incentives Now (GAIN) Act with a Qualified Infectious Disease Product (QIDP) designation, as recommended by the FDA Exclusivity Board.

This adds to the 3 years' exclusivity prevoiusly granted for the approval of Talicia, which is now protected until 2034.

In September 2023, the FDA approved a supplemental New Drug Application (sNDA)

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# Biosimilar Drug Approvals & News

*Continued from Page 44*

Product is expected to be available within two months from this announcement date.

Tyenne is an FDA-approved biosimilar to Actemra® (tocili-zumab) by Genentech, Inc. It is an interleukin-6 (IL-6) receptor antagonist drug, indicated for the treatment of several inflammatory and immune diseases, including rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis.

Tyenne was developed by Fresenius Kabi using advanced analytical and manufacturing technologies.

**Wyost® Injection - First & Only Interchangeable Biosimilar To Xgeva®**

On March 5, Sandoz Inc. of Princeton, New Jersey announced the FDA approval for Wyost® (denosumab-bbdz) Injection 120mg/1.7mL (70mg/mL), approved for all indications of the referenced biosimilar.

This is the ***first and only*** FDA-approved interchangeable biosimilar to Xgeva® (denosumab) Injection by Amgen, Inc.

Wyost has the same dosage form, route of administration, dosing regimen, and presentation as its reference medicine; and is approved as interchangeable to the reference medicine for all indications.

It is indicated for the following: To prevent skeletal-related events (SREs) in patients with multiple myeloma and in patients with bone metastases from solid tumors; to treat adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity; and to treat hypercalcemia of malignancy refractory to bisphosphonate therapy. In pediatric patients it is only recommended only for skeletally mature adolescents with giant cell tumor of bone.

Bones are the third most frequent site for metastatic tumors. Nearly all types of cancer can spread to the bone and cause pain and fractures, though cancers that often metastasize in bones include breast and prostate.

***Also note:*** Advise women of potential risk to the fetus and to use effective contraception during treatment. Also, avoid invasive dental procedures during treatment.

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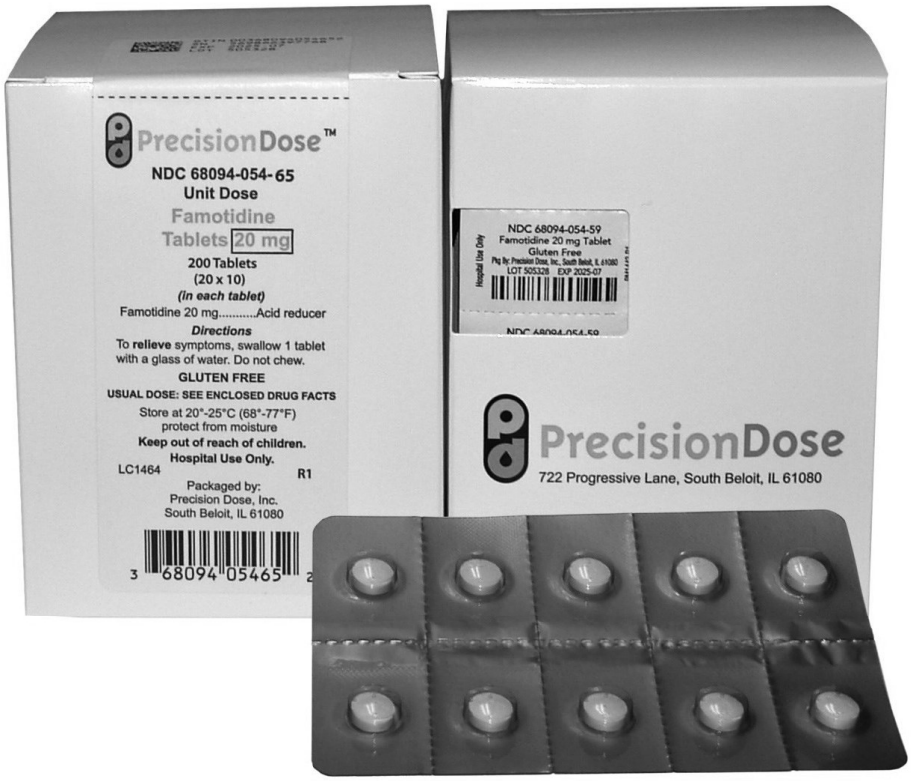
PrecisionDose
Unit-Dose Medications

NEW ITEM

# Famotidine 20mg Tablets
## 20x10 Unit-Dose Blister Cards




- Barcoded Label
- Perforated Cards
- Available Through Your Preferred Wholesaler

| Product | Item Number 68094- | Carton Qty | Cencora | Cardinal | McKesson | Morris & Dickson |
|---|---|---|---|---|---|---|
| Famotidine 20mg Tablets 20x10 Unit-Dose Blister Cards | 0054-65 | 200 | 10288527 | 5914650 | 2933315 | 365874 |

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# Health Disparities Among People In Rural America

On November 7, 2023, the American Heart Association (AHA) of Dallas, Texas announced results from a recent AHA Presidential Advisory, which found that people who live in rural communities live 3 fewer years than those in urban areas; and death rates from heart disease and stroke are noticeably higher among people who live in rural versus metropolitan and urban areas of the country.

Approximately 61 million people, nearly 20% of the U.S. population, currently live in rural areas of the country. The AHA believes that where you live should not determine how long you live.

According to the reported data, people living in rural parts of the U.S. are 40% more likely to develop heart disease and have a 30% higher risk of stroke than people who live in urban areas. Unique health challenges related to individual risk factors, social determinants of health, and lack of access to healthcare drive these disparities.

The advisory notes that some of the factors that contribute to poor health among people in rural areas include the following.

- Physical access to healthcare, including clinical and mental healthcare providers, is often difficult in rural areas due to geographical terrain and a lack of local public transportation.
- Health behaviors that increase cardiovascular risks, such as tobacco use and lack of physical activity, are more common among rural populations, as well as poorer mental health.
- In recent years, the opioid crisis has contributed to soaring rates of drug use and overdose in rural communities, with opioid-related mortality being substantially higher in some rural regions of the country compared to urban areas.
- Social determinants of health contribute to poor cardiovascular outcomes in rural populations, when compared to outcomes in

*Continued on Page 50*

# Legal Product News

*Continued from Page 46*

for Talicia, allowing a change to a more flexible 3 times daily dosing regimen for *H. pylori* eradication. That now enables patients to follow a more convenient "breakfast, lunch, and dinner" dosing routine, which may support increased patient adherence and optimize the potential for successful *H. pylori* eradication.

Talicia is eligible for a total of 8 years of U.S. market exclusivity under its Qualified Infectious Disease Product designation and is also covered by U.S. patents which extend patent protection until 2034, with additional patents and applications pending and granted in various territories worldwide.

### Tafinlar® Patent Infringement Resolved

On December 6, 2023, Daiichi Sankyo, Inc. of Basking Ridge, New Jersey announced their subsidiary Plexxikon, Inc. of South San Francisco, California and Novartis Pharmaceuticals Corporation of East Hanover, New Jersey have settled Plexxikon's U.S. patent infringement lawsuit against Novartis, regarding the sale of Tafinlar® (dabrafenib mesylate) in its multiple forms (by Novartis).

Previously the U.S. District Court of California issued an order sustaining a jury verdict in favor of Plexxikon, finding that Novartis's BRAF inhibitor drug Tafinlar infringes on two of Plexxikon's U.S. patents. Subsequently the Court issued a judgment requiring Novartis to pay Plexxikon in damages, pre and post-judgment interest, and a 9% royalty on U.S. sales of Tafinlar until the expiration of its patents.

On October 27, 2022, Novartis submitted an appeal to the U.S. Federal Appeals Circuit Court seeking review of that judgment.

Pursuant to the settlement, Plexxikon will receive a lump sum payment from Novartis and the appeal will be dismissed.

### Trokendi XR® Capsules - Patent Infringement Settled

On February 5, Supernus Pharmaceuticals, Inc. of Rockville, Maryland announced the U.S. District Court of New Jersey has ruled that Torrent Pharmaceuticals Ltd. and its subsidiary Torrent Pharma Inc. of Basking Ridge, New Jersey, infringed on three U.S. drug patents by submitting an ANDA to the FDA seeking permission to market a generic version of Trokendi XR® (topiramate, extended-release) Capsules, before the expiration of Supernus' patents on the drug.

In addition to the three patents that were the subject of the District Court's decision, Trokendi XR is further protected by seven other patents. The Orange Book lists a total of ten patents as covering Trokendi XR.

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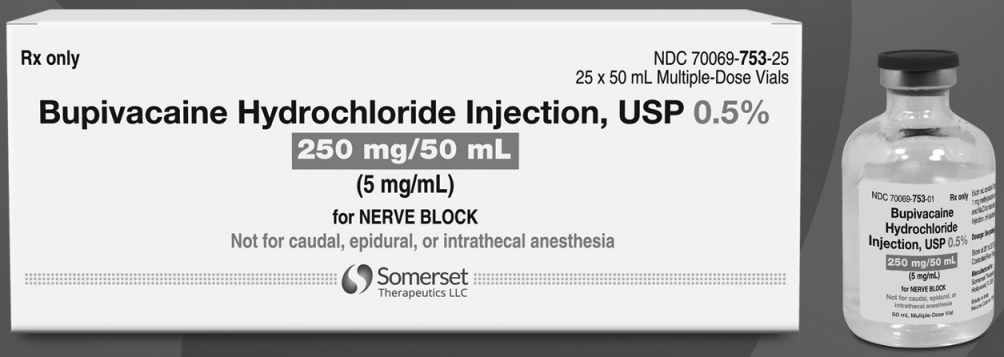


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# Health Disparities In Rural America

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urban populations. Income, education, employment, housing, transportation, and food insecurity all contribute to one's health. Rural populations fare less well on average for all these indicators.

The AHA is working to help increase healthy life expectancy in the rural U.S. by bringing awareness to hypertension prevention, improving access to care, and addressing cardiopulmonary resuscitation (CPR) training and cardiac response times in outlying communities. Telehealth and digitally enabled healthcare is leveraged for patients in communities with broadband, though technology is lagging in the most remote areas.

**Joseph C. Wu,** M.D., Ph.D., FAHA, Volunteer President of the AHA, Director of the Stanford Cardiovascular Institute Simon H. Stertzer Professor of Medicine & Radiology at the Stanford School of Medicine in California, remarked: "The AHA is cognizant to the fact that America's rural regions are very unique and that there's not a one-size-fits-all approach to eliminating rural health disparities. While there are some commonalities among rural areas, we must tailor our strategies to meet the needs of all communities from the Arkansas Delta to the prairies of Wyoming, the plains of Texas, to the mountains of Appalachia, and beyond. Within a matter of miles, people can have vastly different experiences that impact their health outcomes."

While most rural communities are predominantly White (80%), there are significant race and ethnicity differences across the country. According to a report from the Pew Research Center in Washington, D.C., the rural South has a large population of non-Hispanic Black individuals; the rural Southwest is home to many Hispanic individuals and rural Oklahoma; Alaska, the Great Plains, and the Southwest are home to high percentages of American Indian/Alaska Native individuals. Rural areas also have a higher percentage of elderly individuals and experience lower population growth and higher rates of poverty compared to urban and suburban populations.

Dr. Wu stated, "Addressing the unique needs of rural populations to improve health and well-being is critically important for the overall health and well-being of the nation. Broad, innovative, and sustained approaches are needed that address the tough underlying structural, social, and policy issues that have challenged other areas of the country and healthcare systems and have manifested themselves as particularly severe and vexing in rural areas and populations."

The AHA has an ongoing commitment to improving the health and healthcare access of people living in rural America and continues to add new initiatives targeting these special challenges.

- With support from the Helmsley Charitable Trust of New York City and from Public Health AmeriCorps with nationwide locations, a partnership between AmeriCorps and the U.S. Centers for Disease Control & Prevention (CDC), the AHA launched HeartCorps, an initiative to support the recruitment, training, and development of a new generation of public health leaders. Plans call for 100 HeartCorps members to be deployed to many rural communities comprising 30 states across the country (see the full list of states at https://americorps.gov/funded-grants/public-health-americorps). The program will prioritize areas with high rates of uncontrolled blood pressure or cardiovascular disease, increased social vulnerability, and shortages of health professionals.
- In June 2023, the AHA awarded $20 million in research funding through the Health Equity Research Network on Improving Access to Care and other Health Inequities in Rural America. This research initiative comprises a network of special projects focused on advancing the understanding of the factors that impact health in rural America.
- Last year, the AHA launched its Rural HealthCare Outcomes Accelerator to provide up to 700 rural hospitals with no-cost access to Get With The Guidelines® quality programs for coronary artery disease, heart failure, and stroke. In addition, they established a rural recognition program for these hospitals to assist in communicating their commitment to care excellence with the communities they serve.

The AHA is continually working to improve health in rural areas of the U.S. and around the world.

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# News Briefs

### AbbVie To Acquire Landos Biopharma

On March 25, AbbVie Inc. of North Chicago, Illinois and Landos Biopharma, Inc. of New York City jointly announced a definitive agreement under which AbbVie will acquire Landos.

The acquisition is expected to close in the second quarter of 2024.

Landos is a clinical stage biopharmaceutical company focused on the development of novel, oral therapeutics for patients with autoimmune diseases. Their lead investigational asset is NX-13, a first-in-class, oral NLRX1 agonist (a member of the NOD-like receptor family) with a bimodal mechanism of action, which is anti-inflammatory and facilitates epithelial repair.

**Roopal Thakkar,** M.D., Senior VP & Chief Medical Officer of Global Therapeutics for AbbVie, commented: "With this acquisition, we aim to advance the clinical development of NX-13, a differentiated, first-in-class, oral asset with the potential to make a difference in the lives of people living with ulcerative colitis and Crohn's disease."

### Gilead Sciences Completes Acquisition Of CymaBay

On March 22, Gilead Sciences, Inc. of Foster City, California announced they completed the acquisition of CymaBay Therapeutics, Inc. of Newark, California.

As a result of the merger, CymaBay has become a wholly owned subsidiary of Gilead.

The addition of CymaBay's investigational lead product candidate, seladelpar, for the treatment of primary biliary cholangitis including pruritus, complements Gilead's existing liver portfolio and aligns with its long-standing commitment to bringing transformational medicines to patients.

**Daniel O'Day,** Chairman & CEO of Gilead Sciences, commented: "The acquisition of CymaBay brings us a potential best in disease therapy that could transform the treatment landscape for people with primary biliary cholangitis."

### AstraZeneca To Acquire Fusion Pharmaceuticals

On March 19, AstraZeneca USA of Wilmington, Delaware and Fusion Pharmaceuticals, Inc. of Boston, Massachusetts (with a second North American location in Ontario, Canada) jointly announced they have entered into an agreement whereby Fusion will be acquired by AstraZeneca.

Fusion is a clinical-stage oncology company focused on developing next-generation radioconjugates (RCs) as precision medicines.

RCs have emerged as a promising modality in cancer treatment over recent years. These medicines deliver a radioactive isotope directly to cancer cells through precise targeting using molecules such as antibodies, peptides, or small molecules. This approach has many potential advantages compared to traditional radiotherapy, including minimizing damage to healthy cells and enabling access to tumors not reachable through external beam radiation.

The acquisition brings new expertise and pioneering R&D, manufacturing, and supply chain capabilities in actinium-based RCs to AstraZeneca. It also strengthens their presence in and commitment to Canada. Fusion will become a wholly owned subsidiary of AstraZeneca, with operations continuing in Canada and the United States.

**Susan Galbraith,** Executive VP of Oncology R&D at AstraZeneca, said: "Between 30% and 50% of patients with cancer today receive radiotherapy at some point during treatment, and the acquisition of Fusion furthers our ambition to transform this aspect of care with next-generation RCs. Together with Fusion, we have an opportunity to accelerate the development of FPI-2265 as a potential new treatment for prostate cancer, and to harness their innovative actinium-based platform to develop RCs as foundational regimens."

### Merck To Acquire Harpoon Therapeutics

On March 11, Merck & Co., Inc. of Rahway, New Jersey and Harpoon Therapeutics, Inc. of South San Francisco, California jointly announced the completion of the acquisition of Harpoon Therapeutics.

The companies entered into a definitive agreement in January under which Merck, through a subsidiary, would acquire Harpoon which has now become a wholly owned subsidiary of Merck.

Harpoon Therapeutics is a clinical-stage immunotherapy company that has developed a portfolio of novel T-cell engagers that employ their proprietary Tri-specific T-cell Activating Construct (TriTAC®) platform, an engineered protein technology designed to direct a patient's own immune cells to kill tumor cells. The ProTriTAC™ platform, applying a prodrug concept to its TriTAC platform, creates a therapeutic T-cell engager that is designed to remain inactive until it reaches the tumor.

### Johnson & Johnson Completes Acquisition Of Ambrx Biopharma

On March 7, Johnson & Johnson of New Brunswick, New Jersey and Ambrx Biopharma, Inc. of San Diego, California jointly announced that Johnson & Johnson has successfully completed the acquisition of Ambrx.

Ambrx is a clinical-stage biopharmaceutical company with a proprietary synthetic biology technology platform to design and develop next-generation antibody drug conjugates.

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This business combination presents a distinct opportunity for Johnson & Johnson to design, develop, and commercialize targeted oncology therapeutics. Ambrx's proprietary antibody drug conjugate (ADC) technology incorporates the advantages of highly specific targeting monoclonal antibodies securely linked to a potent chemotherapeutic payload to achieve targeted and efficient elimination of cancer cells without the prevalent side-effects typically associated with chemotherapy.

**Yusri Elsayed,** M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head of Oncology for J&J Innovative Medicine, said: "Ambrx's ADC technology offers unique advantages in the conjugation of stable antibodies and cytotoxic linker payloads, which results in engineered ADCs that effectively kill cancer cells and limit toxicities."

### AstraZeneca Acquires Gracell Biotechnologies

On February 22, AstraZeneca USA of Wilmington, Delaware and Gracell Biotechnologies, Inc. of San Diego, California jointly announced the successful completion of the acquisition of Gracell by AstraZeneca.

Gracell is a global clinical-stage biopharmaceutical company developing innovative cell therapies for the treatment of cancer and autoimmune diseases.

The acquisition enriches AstraZeneca's growing pipeline of cell therapies with GC012F, a novel, clinical-stage FasTCAR-enabled BCMA and CD19 dual-targeting autologous chimeric antigen receptor T-cell (CAR-T) therapy. GC012F is a potential new treatment for multiple myeloma, as well as other haematologic malignancies and autoimmune diseases including systemic lupus erythematosus (SLE).

Gracell will operate as a wholly owned subsidiary of AstraZeneca, with operations in China and the United States.

### Rigel Pharmaceuticals To Acquire Gavreto® Capsules

On February 22, Rigel Pharmaceuticals, Inc. of South San Francisco, California announced they have entered into a definitive agreement to acquire the U.S. rights for Gavreto® (pralsetinib) Capsules from Blueprint Medicines Corporation of Cambridge, Massachusetts.

Rigel expects to complete the transition in the third quarter of 2024.

Gavreto is a once daily, small molecule, oral, kinase inhibitor of wild-type RET (rearranged during transfection) and oncogenic RET fusions. It is FDA-approved for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test.

Rigel expects to complete the transition of Gavreto and start recognizing product sales in the third quarter of 2024. Current and newly prescribed patients will be able to access Gavreto without interruption through the transition period.

**Raul Rodriguez,** President & CEO of Rigel, said: "NSCLC is the most common type of lung cancer in the U.S. with RET fusions representing 1% to 2% of the patient population. Gavreto is a targeted treatment option with an established safety profile that has shown durable responses in RET fusion-positive NSCLC patients."

### AstraZeneca Acquires Icosavax

On February 19, AstraZeneca USA of Wilmington, Delaware announced the successful completion of the acquisition of Icosavax, Inc. of Seattle, Washington.

Icosavax is a U.S. based clinical-stage biopharmaceutical company focused on developing differentiated, high-potential vaccines using an innovative, protein virus-like particle (VLP) platform.

Icosavax is a U.S. based clinical-stage biopharmaceutical company, is focused on developing differentiated, high-potential vaccines using an innovative, protein virus-like particle (VLP) platform. As VLP vaccines mimic how naturally occurring viruses appear to the body's immune system, they may offer potential benefits over non-VLP vaccines, including a stronger immune response, greater breadth of protection, greater durability requiring fewer boosters, and compared to the current adjuvanted respiratory syncytial virus (RSV) vaccine, a lower incidence of side effects.

The acquisition builds on AstraZeneca's expertise in RSV, strengthening their Vaccines & Immune Therapies late-stage pipeline with Icosavax's lead investigational vaccine candidate, IVX-A12. This product is a potential first-in-class, Phase III-ready, combination protein VLP vaccine which targets both RSV and human metapneumovirus (hMPV), two leading causes of severe respiratory infection and hospitalization in adults 60 years of age and older and those with chronic conditions such as cardiovascular, renal, and respiratory disease. There are currently no treatments or preventative therapies for hMPV and no combination vaccines for RSV.

**Iskra Reic,** Executive VP of Vaccines & Immune Therapies at AstraZeneca, said: "This VLP vaccine technology has the potential to transform prevention against severe infectious diseases, including RSV and hMPV. With the addition of Icosavax's Phase III-ready lead asset to our late-stage pipeline, we will have a differentiated, advanced investigational vaccine, and a platform for further development of

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combination vaccines against respiratory viruses. This fits our mission to address high unmet needs in infectious diseases, and our ambition to protect the most vulnerable patients who have high risk of severe outcomes."

### AbbVie Completes Acquisition Of ImmunoGen

On February 12, AbbVie Inc. of Chicago, Illinois announced they have completed the acquisition of ImmunoGen, Inc. of Waltham, Massachusetts, in which ImmunoGen is now part of AbbVie.

ImmunoGen's pipeline complements AbbVie's existing oncology pipeline with potential to be transformative across multiple solid tumors and hematologic malignancies. This includes the acquisition of Immunogen's Elahere® (mirvetuximab soravtansine-gynx) Injection, the first and only FDA-approved antibody-drug conjugate (ADC) indicated in ovarian cancer.

**Robert A. Michael,** President Chief Operating Officer of AbbVie, said: "Together with ImmunoGen, we have the potential to continue redefining the standard of care for those living with cancer."

### Tlando® Caps (C-III) - Now Marketed By Verity Pharma

On February 2, Lipocine Inc. of Salt Lake City announced the commercialization of Tlando® (testosterone undecanoate) Capsules in the U.S. has now been transitioned to its licensee Verity Pharma of Ewing, New Jersey, effective February 1, 2024, enabling the continuity of patient access.

Tlando is the first and only oral testosterone replacement therapy (TRT) option approved by the FDA that does not require dose titration. It was developed using Lipocine's proprietary Lip'ral drug delivery technology platform.

Testosterone has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 3 (C-III) controlled drug substance and is indicated for TRT in adult males for conditions associated with a deficiency or absence of endogenous testosterone such as primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (either congenital or acquired).

Under the terms of the agreement, Verity Pharma will be responsible for regulatory and marketing obligations in the U.S. and all further development. Lipocine retains all rights to the Tlando franchise for territories outside the U.S. and Canada, and all rights to non-TRT indications globally.

### Sanofi To Acquire Inhibrx

On January 23, Sanofi of Cambridge, Massachusetts and Inhibrx, Inc. of San Diego, California jointly announced they have entered into a definitive agreement, under which Sanofi has agreed to acquire Inhibrx following the spin-off of non-INBRX-101 assets into New Inhibrx.

New Inhibrx will retain non-INBRX-101 assets, notably including its immuno-oncology pipeline, as well as Inhibrx assets not related to INBRX-101 and Inhibrx's employees.

The transaction is expected to close in the second quarter of 2024.

The company will be led by **Mark P. Lappe** (Founder & CEO of Inhibrx), to now be the Chairman & CEO of New Inhibrx, which will continue to operate under the Inhibrx name.

INBRX-101 is a human recombinant protein that holds the promise of allowing Alpha-1 Antitrypsin Deficiency (AATD) patients to achieve normalization of serum AAT levels with less frequent dosing. AATD is an inherited rare disease characterized by low levels of AAT protein that predominantly affect the lung with progressive deterioration of the tissue. INBRX-101 may help to reduce inflammation and prevent further deterioration of lung function in those affected.

Inhibrx is a clinical-stage biopharmaceutical company focused on developing a broad pipeline of novel biologic therapeutic candidates in oncology and orphan diseases. They utilize diverse methods of protein engineering to address the specific requirements of complex target and disease biology, including its proprietary protein engineering platforms.

### Eli Lilly Completes Acquisition Of POINT Biopharma

On December 27, 2023, Eli Lilly & Company of Indianapolis, Indiana announced the successful completion of their acquisition of POINT Biopharma Global Inc. also of Indianapolis.

POINT is a radiopharmaceutical company with a pipeline of clinical and preclinical-stage radioligand therapies in development for the treatment of cancer.

**Jacob Van Naarden,** Executive VP & President of Loxo@Lilly, said: "Next generation radioligand therapies hold great promise for delivering meaningful advances against a range of cancers and we are excited to enter this space through the addition of POINT."

### Bristol Myers Squibb To Acquire RayzeBio

On December 26, 2023, Bristol Myers Squibb of Princeton, New Jersey and RayzeBio, Inc. of San Diego, California jointly announced a definitive merger agreement under which Bristol Myers Squibb will acquire RayzeBio.

RayzeBio is a clinical-stage radiopharmaceutical therapeutics company with current pipeline programs which target the treatment of solid

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tumors, including gastroenteropancreatic neuroendocrine tumors, small cell lung cancer, hepatocellular carcinoma, and other cancers.

There remains a high, unmet need for more effective treatments in solid tumors, and RPTs enable a precision approach to patient treatment which bind to tumor cells and deliver targeted radiation to induce cancer cell death. Actinium-based RPTs offer potential advantages over currently available RPTs since the high potency and short firing range of the alpha-emitter create the possibility for stronger efficacy and more targeted delivery.

RayzeBio is completing construction of a state-of-the-art in-house manufacturing facility in Indianapolis and drug production is expected to begin in the first half of 2024.

**Ken Song,** M.D., President & CEO of RayzeBio, stated: "Despite therapeutic advances in recent years, the need for more effective treatments in solid tumors persists, and radiopharmaceutical therapeutics are positioned to be an important next wave of innovation in oncology therapy."

Closing of the transaction should be completed by mid-2024.

### Astellas Pharma Acquires Propella Therapeutics

On December 21, 2023, Astellas Pharma US, Inc. of Northbrook, Illinois announced they completed the acquisition of Propella Therapeutics, Inc. of Pittsboro, North Carolina, making Propella a wholly owned subsidiary of Astellas.

A privately held biopharmaceutical company, Propella leveraged a wholly owned proprietary platform which combines medicinal chemistry with lymphatic targeting to create new oncology drugs.

Through the acquisition, Astellas has acquired PRL-02 (abiraterone decanoate), a next-generation androgen biosynthesis inhibitor being developed by Propella to treat prostate cancer.

**Naoki Okamura,** President & CEO of Astellas, commented: "The acquisition fits with Astellas' strategy to provide patients with therapeutic options for diseases with high unmet medical needs. Propella has a promising program, PRL-02, targeting prostate cancer. We believe that the synergy with Astellas' global development and commercialization capabilities in the cancer and urology fields will accelerate the development of PRL-02 and deliver new options to patients with prostate cancer."

### Zimhi® Injection - Full Commercial Rights Regained By DMK Pharmaceuticals

On December 21, 2023, DMK Pharmaceuticals Corporation of San Diego, California announced it has regained the full rights to commercialize Zimhi® (naloxone) Injection for intramuscular or subcutaneous use, after the termination of an exclusive commercialization and distribution agreement with US WorldMeds, LLC of Louisville, Kentucky.

DMK is a commercial stage neuro-biotech company that is primarily focused on developing and commercializing products for the treatment of opioid overdose and substance use disorders. They are now actively seeking commercialization opportunities for Zimhi. In the U.S., first responders are the primary target for Zimhi, where market data demonstrates a significant, unmet demand.

### Pfizer Completes Acquisition Of Seagen

On December 14, 2023, Pfizer Inc. of New York City announced the successful completion of their acquisition of Seagen Inc. of Bothell, Washington, a global biotechnology company that discovers, develops, and commercializes transformative cancer medicines.

With the addition of Seagen's four in-line injectable medicines: Adcetris® (brentuximab vedotin), Padcev® (enfortumab vedotin), Tivdak® (tisotumab vedotin), and Tukysa® (tucatinib), Pfizer's oncology portfolio now includes over 25 approved medicines and biosimilars across more than 40 indications.

**Albert Bourla,** Pfizer Chairman & CEO, said: "Cancer remains a leading cause of death, and 1 in 3 Americans have a cancer diagnosis in their lifetime. Pfizer is going all in on cancer treatments, with the goal of delivering breakthroughs that drastically improve the lives of people with cancer."

### Ongentys® Capsules - New Licensing Agreement

On December 7, 2023, Amneal Pharmaceuticals, Inc. of Bridgewater, New Jersey and Bial Biotech Investments Inc. in Cambridge, Massachusetts jointly announced a new licensing agreement, whereby Amneal will have exclusive rights to market and distribute Ongentys® (opicapone) Capsules in the United States, beginning December 18, 2023.

Amneal expects to begin distribution of Ongentys in early 2024.

Ongentys is BIAL's proprietary once-daily, peripherally acting, highly selective catechol-O-methyltransferase inhibitor drug that was FDA-approved in 2020 as an add-on treatment to carbidopa/levodopa in patients with Parkinson's disease (PD) experiencing "Off" episodes.

Carbidopa/levodopa (CD/LD), which works to control the symptoms of PD, has been the gold-standard treatment for PD since the

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1970s. As the disease progresses, patients on LD start experiencing motor complications such as the "wearing-off phenomenon," which are periods where LD is no longer providing enough relief from PD symptoms and people experience what is referred to as "Off" time. Wearing-off is common, with around 50% of patients reporting it in the first 5 years after PD diagnosis. "Off" time can greatly disrupt a patient's daily routine by inhibiting their ability to perform tasks or care for themselves.

Ongentys offers patients living with Parkinson's disease an effective, once-daily adjunctive treatment option for "Off" episodes. It is the first and only LD optimizer approved for once-daily use.

### Ponvory® Rights Acquired By Vanda Pharmaceuticals

On December 7, 2023, Vanda Pharmaceuticals, Inc. of Washington, D.C. announced that it has acquired the U.S. rights to Ponvory® (ponesimod) Tablets from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company.

Under the terms of the agreement, Janssen will continue to operate the business pursuant to a Transitional Business License Agreement, during which time, Vanda and Janssen will transition regulatory and supply responsibility for Ponvory to Vanda.

### Johnson & Johnson MedTech Acquires Laminar

On November 30, 2023, Johnson & Johnson (J&J) MedTech of New Brunswick, New Jersey announced the completion of the acquisition of Laminar, Inc. of Santa Rosa, California, a privately held medical device company focused on eliminating the left atrial appendage in patients with non-valvular atrial fibrillation.

Laminar joins J&J MedTech as part of Biosense Webster, Inc. of Irvine, California—a global leader in cardiac arrhythmia treatment.

Approximately 38 million patients around the world are living with atrial fibrillation (AFib), which causes them to be more than 5 times as likely to have a stroke. The left atrial appendage (LAA) is a small pouch in the left atrium of the heart and can be a source of clots that can enter the blood stream, potentially causing a stroke. The LAA is a major contributor to thromboembolic stroke in patients with non-valvular atrial fibrillation. Unlike current commercial catheter-based procedure devices that use plugs to occlude the LAA, Laminar's novel approach uses rotational motion to eliminate the LAA.

### Symjepi® Injection Full Rights Regained By DMK Pharmaceuticals

On November 28, 2023, DMK Pharmaceuticals Corporation of San Diego, California announced they have reacquired the rights to their Symjepi® (epinephrine) Injection 0.15mg and 0.3mg products from US WorldMeds, LLC of Louisville, Kentucky.

Previously, US WorldMeds held exclusive distribution and commercialization rights for Symjepi and Zimhi® (naloxone) Injection products in the United States, and was responsible for marketing, promotion, and distribution efforts.

DMK is now actively seeking out-license opportunities for Symjepi in the U.S. and globally, in addition to exploring other options with a focus on maximizing value for shareholders.

A commercial stage neuro-biotech company, DMK is focused on developing and commercializing products for the treatment of opioid overdose and substance use disorders and other important neuro-based conditions where patients are currently underserved.

### Alkermes Completes Separation Of Oncology Business

On November 15, 2023, Alkermes, Inc. of Cambridge, Massachusetts announced it has completed the separation of its oncology business into Mural Oncology plc of Dublin, Ireland (with U.S. headquarters in Waltham, Massachusetts), a new and independent, publicly traded company.

Alkermes works to develop innovative medicines for people living with difficult to treat psychiatric and neurological disorders.

### Mural Oncology Now An Independent Immuno-Oncology Company

On November 15, 2023, Mural Oncology plc of Dublin, Ireland (with U.S. headquarters in Waltham, Massachusetts) announced their launch as a newly independent, publicly traded, clinical-stage immuno-oncology company leveraging its core competencies in immune cell modulation and protein engineering to develop novel, investigational engineered cytokine therapies designed to address areas of unmet need for patients with a variety of cancers.

Mural Oncology's pipeline is built to address difficult-to-treat tumor types when checkpoint inhibitors are not effective. Their lead product candidate, nemvaleukin alfa (nemvaleukin), is an investigational, engineered interleukin-2 (IL-2) cytokine designed to capture and expand the therapeutic benefits of high-dose recombinant human IL-2 (rhIL-2), while mitigating the hallmark toxicities of native IL-2 in difficult-to-treat cancers with high unmet need.

# Fun Las Vegas Events/Dining Info

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an odd row here or there. We have also moved the bars and the food placement a bit. The front of the hall will still have snacks and ice cream with the bar. The back corners also have snacks, a bar, and ice cream if you care to grab a little nibble as you wander through. We want the experience to be fundamentally better for both you as well as for the exhibitors.

Each year we have new pharmacy attendees joining us. We especially want to ensure that the new attendees have a great time for their first visit to our NPPA Conference. If you see someone wearing a ribbon on their name badge that states they're a new attendee, please welcome them and say hello. Perhaps even ask if you can help them with any questions they may have as well, which all helps to make them not feel as nervous being their first time and being there on their own in many cases. And if you are new and need any help whatsoever, please reach out to any of our NPPA staff so we can assist you. We even have some veteran longtime members and attendees who have told us to go to them for any introductions and guidance for our newbies. We want everyone to feel welcome and to have an amazing time!

Additionally, I wanted to share some of my own personal things that I enjoy about Las Vegas. For instance, I didn't always know how easy the monorail was to use, and fun! It travels down the length of the Strip, from MGM Grand on one end all the way down to the other end where the Westgate Hotel is (the old LV Hilton). And our headquarters at Horseshoe hotel is conveniently one of the stops on the monorail route, which makes it so easy to head down the escalators and walk through and past the shopping mall to get to the monorail entrance. The monorail opens at 7am and runs until 2am. They also have day passes or multi-day passes for a discounted rate. It almost feels like I'm riding the subway in New York City! Here is the site page for all of the monorail info: www.lvmonorail.com

Then I usually try to see a show when I have the time, and Las Vegas has show options for literally everyone. Last year, I attended the Mad Apple show at NY/NY Casino. It's adult humor and no one under the age of 18 is allowed. I thought it was fantastic. Another

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**Caroline Loew,** Ph.D., CEO of Mural Oncology, said: "Immunotherapies have made a tremendous impact on the treatment of cancers over the past decade. Unfortunately, many patients either do not respond or do not have durable responses. We believe Mural Oncology can lead the future of immunotherapies for patients. Our protein engineering expertise allows us to reimagine the development of pro-inflammatory cytokine-based therapeutics that could address the key limitations with current cancer immunotherapies."

**Alfasigma Completes Acquisition Of Intercept Pharmaceuticals**

On November 8, 2023, Alfasigma S.p.A. of Bologna, Italy (with U.S. headquarters in Bedminster, New Jersey) and Intercept Pharmaceuticals, Inc. of Morristown, New Jersey jointly announced the completion of the acquisition of Intercept by Alfasigma.

As a result of the transaction, Intercept has become a wholly owned subsidiary of Alfasigma.

With this transaction, Alfasigma adds Ocaliva® (obeticholic acid) Tablets to its portfolio, the only second-line treatment approved by the FDA for primary biliary cholangitis; a progressive autoimmune disease affecting the liver.

**Francesco Balestrieri,** CEO of Alfasigma, stated: "We hope this strengthened innovation and R&D pipeline, including the addition of a novel fixed-dose combination of obeticholic acid and bezafibrate, gives us the potential to establish a new paradigm in the treatment of patients with primary biliary cholangitis."

**PAI Pharma Acquires VistaPharm**

On November 3, 2023, Pharmaceutical Associates Inc. (PAI) of Greenville County, South Carolina announced the acquisition of VistaPharm LLC of Parsippany, New Jersey—a privately held, healthcare company that offers generic pharmaceuticals and over the counter products for hospitals, retail pharmacies, and the specialized clinical setting.

Since 2001, VistaPharm has been dedicated to improving the lives of patients struggling with addiction. Now as a PAI Pharma company, they will remain the distributor and only full-line wholesaler of pharmaceutical products to opioid treatment program (OTP) clinics. Their product portfolio will continue to offer a wide range of addiction treatment medications, including different dosage forms and strengths of methadone, buprenorphine, and naloxone-based products.

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# Fun Las Vegas Events/Dining Info

*Continued from Page 57*

year, I discovered a brand-new show by the Illuminate group at the Stratosphere hotel, who were on the TV show America's Got Talent, which was quite amazing and had a great energy to it. Las Vegas shows have everything you can imagine. They have at least 20 top-selling events that I found. To see what they currently have to offer, visit: www.vegas.com/shows

Now, the food in Las Vegas, let us face it, can be overwhelming with all of the options and how good it is! Jonathan here at NPPA and I usually start looking at possibilities for where we'd like to dine while there months in advance, then narrow the list down as we get closer to the show start in order to make some reservations if needed or just have a plan in mind. We usually have favorites we hit every year but also add some new places in as well, to broaden our palettes! We always eat somewhere in the Paris and Horseshoe hotels, as well as the cafes and high-end fast food places in the outdoor mall area in front of Horseshoe. At NY/NY hotel, we absolutely love their Chin-Chin restaurant. This year we are planning to try a new pizza place that I found watching an Instagram post about it that looked good. Then there's the Duck Donuts outside of Horseshoe that we traditionally get for our Sunday staff setup workday! Post-conference, we always go to Blueberry Hill for breakfast, a stand-alone diner type place not associated with a hotel, that has a few different locations around the Strip and Vegas. If you ever need ideas, just ask us! We are happy to share our adventures with anyone who may need help finding a new great place to eat.

Now this next part is for those of you who arrive earlier or stay a bit longer post conference and might be looking to get out in nature for some peace and quiet off the beaten path. I actually used to live in Las Vegas for a few years, during my military stint and afterwards. My calming place to get away from the noise of life and chaos is The Red Rock Canyon National Conservation Area (RRCNCA), located just a few miles west of Las Vegas and encompasses 195,819 acres within the Mojave Desert.

Red Rock Canyon is an area of worldwide geologic interest and beauty, a real painted desert. You can hike or drive through it (if you're worried about the heat), and wander through the areas without issue or too much exertion. I take pictures every visit. It calms me, soothes my soul, and invigorates my energy levels. If you have a chance, you will not regret it. Check out the pictures and more info, here: www.redrockcanyonlv.org/visitor-information

All of the team here at NPPA sincerely want you to enjoy our Annual Conference. If we can be of help for anything, please let us know so we can make your attendance and Vegas visit a memorable and enjoyable one!

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# Vemlidy® Tabs For Chronic HBV In Pediatric Patients

On March 28, Gilead Sciences, Inc. of Foster City, California announced the FDA approved the supplemental New Drug Application (sNDA) for Vemlidy® (tenofovir alafenamide) Tablets 25mg, now also indicated as a once-daily treatment for chronic hepatitis B virus infection in pediatric patients 6 years of age and older and weighing at least 25kg with stable (compensated) liver disease.

Hepatitis B (HBV) is a serious disease that attacks the liver and can cause chronic (lifelong) infection, cirrhosis of the liver, liver cancer, and evem death in up to a third of patients. Hepatitis B is spread through infected blood or body fluids, sexual contact, injection drug use, or perinatally from mother to child. Early symptoms may include loss of appetite, fever, generalized aches and pains, fatigue, itching, urticaria (hives), and joint pain. The disease is often asymptomatic, which may lead to undiagnosed individuals. Later symptoms may include nausea and vomiting, halitosis (bad breath), dark brown urine, jaundice (yellowing of the skin and eyes), and right-sided abdominal pain (especially with external pressure or palpitation).

Vemlidy is a targeted prodrug of tenofovir that was approved by the FDA in 2016 as a once-daily treatment for adults with chronic HBV infection with compensated liver disease. In 2022, the FDA approved Vemlidy for the treatment of chronic HBV infection in pediatric patients 12 years of age and older with compensated liver disease. Vemlidy is recommended as a preferred or first-line treatment for adults with chronic HBV with compensated liver disease by the American Association for the Study of Liver Diseases (AASLD) and European Association for the Study of the Liver (EASL) guidelines.

**Chuan-Hao Lin,** M.D., Associate Professor of Clinical Pediatrics at the Krek School of Medicine of the University of Southern California (USC) in Los Angeles, said: "Chronic hepatitis B can have a significant and lasting impact on the health of children. If left untreated, hepatitis B can lead to liver cirrhosis and liver cancer. As a clinician, I am well aware of the critical importance of promptly treating this disease to avoid possible complications and liver damage. The clinical trial demonstrated that tenofovir alafenamide may represent an effective treatment option for children as young 6 six years old who are affected by this chronic disease."

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# New Updates To ISMP High-Alert Medication List For 2024

On January 12, The Institute for Safe Medication Practices (ISMP) announced they have published an updated new version of its "high-alert" medication list, for their yearly "List of High-Alert Medications in Acute Care Settings-2024."

- The main addition to the new year's high-alert list is the inclusion of the medication **Tranexamic Acid Injection,** which is an antifibrinolytic drug used in a variety of hemorrhagic conditions in order to control bleeding, including with postpartum hemorrhage.
- In addition, both **Potassium Phosphate for Injection** and **Oxytocin Injection** medications are also now included as high alert medications.

High-alert medications are defined as those that bear a heightened risk of causing significant patient harm when used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error involving them may be more devastating to patients. The list includes input from safety experts as well as from a nationwide survey.

Respondents to ISMP's most recent survey (in 2023) shared that errors involving Tranexamic Acid for Injection are frequently related to storage issues and mix-ups with look-alike medication vials. Most often being anesthetics that are also commonly stored in surgical and procedural locations. When accidentally administered via a neuraxial route, tranexamic acid injection is a potent neurotoxin with a mortality rate of about 50%, and almost always harmful to the patient.

Before this update, ISMP had repeatedly warned about errors with Tranexamic Acid, including issuing a National Alert Network warning about it (as found on ISMP's website at www.ismp.org/node/20154). They also published a feature article about it in their *ISMP Medication Safety Alert! Acute Care* newsletter (www.ismp.org/node/8706).

Respondents to the 2023 survey also shared their opinions that two additional medications: Potassium Phosphate for Injection and Oxytocin, should likely be classified as high alert medications, which are both now in the new 2024 list as well.

ISMP published its first compilation of high-alert medications in 1989, which were only 6 total at the time, and those drugs are still on ISMP's list today (along with all many others added since).

**Shannon Bertagnoli,** PharmD, Medication Safety Specialist at ISMP, commented: "We are pleased to see that increasing level of awareness of high-alert status, since knowledge of risk and implementing safeguards can help prevent potentially fatal errors."

To view the full and detailed new 2024 List of High-Alert Medications, visit the ISMP website, at: www.ismp.org/recommendations/high-alert-medications-acute-list (note that ISMP requires you to be registered for an account with them to access the list).

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# Heart Health News

### High Heat May Increase Inflammation & Weaken Immune System

On March 19, the American Heart Association (AHA) of Dallas, Texas announced results of new research revealing short-term exposure to higher heat may increase inflammation and interfere with normal immune system functions in the body. This may in turn increase susceptibility to infections and accelerate the progression of cardiovascular disease.

Inflammation is a normal part of the body's defenses against injury or infection, however, an inflammatory response that is longstanding (lasting weeks to months), or that occurs in healthy tissues is damaging and plays a key role in the build-up of plaque in the arteries. This may lead to atherosclerosis. Heat waves are known to promote inflammation, however, studies examining air temperature and biomarkers of inflammation have had mixed results.

Adults older than age 60 and adults with existing cardiovascular disease are particularly at risk for heat-related cardiovascular events and deaths. During heat waves, people can reduce their exposure by staying indoors when temperatures are highest and the sun is strongest; seeking shade; wearing light, breathable clothing; and drinking plenty of water.

Participants visited study sites in Louisville during the summer months for a blood test, and researchers analyzed the blood for multiple markers of immune system function. The researchers then examined associations between the markers of immune system function and heat levels, including temperature, net effective temperature (which factors in relative humidity, air temperature, and windspeed), and the Universal Thermal Climate Index (UTCI) on that day. UTCI is a thermo-physiological model developed by the International Society of Biometeorology Commission that factors in temperature, humidity, wind speed, and ultraviolet radiation levels, which was used to evaluate participant's physical comfort.

The study analysis found the following.

- For every 5-degree increase in UTCI (in this study, the equivalent of going from a day with no thermal stress to a day with moderate thermal stress), there was an increase in

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the levels of key markers of inflammation: monocytes (4.2%), eosinophils (9.5%), natural killer T-cells (9.9%), and tumor necrosis factor-alpha (7.0%) in the blood. These immune molecules indicate activation of the body's innate immune system, which spurs a fast and non-specific inflammatory response throughout the body to protect against pathogens and injury.

- A decrease in B-cells (-6.8%), indicating the body's adaptive immune system that remembers specific viruses and germs and creates antibodies to fight them, was lowered.
- A lesser impact on the immune system was found when heat was measured by average 24-hour temperature or by net effective temperature, which incorporates humidity and wind but not sunshine.

**Daniel W. Riggs,** Ph.D., Assistant Professor of Medicine in the Christina Lee Brown Envirome Institute at the University of Louisville in Kentucky (and lead study author), noted: "Our study participants only had minor exposure to high temperatures on the day of their blood test, however, even minor exposure may contribute to changes in immune markers. With rising global temperatures, the association between heat exposure and a temporarily weakened response from the immune system is a concern because temperature and humidity are known to be important environmental drivers of infectious, airborne disease transmission. Thus, during the hottest days of summer people may be at higher risk of heat exposure, they may also be more vulnerable to disease or inflammation. It's important for physicians to communicate with patients about the risk of adverse health effects from heat exposure. For example, cardiologists could conduct customized consultations and assessments to increase patient awareness about their susceptibility to the effects of high temperatures. Also, changes to treatment regimens may be important to consider to address other risks. For example, some medications could make people more susceptible to heat-related illness or some may not be as effective when the body is exposed to high temps."

### Time-Restricted Eating Linked To Higher Risk Of Cardiovascular Death

On March 18, the American Heart Association (AHA) announced new research findings from an analysis of over 20,000 U.S. adults, which found that people who limited their eating across less than 8 hours per day (a time-restricted eating plan) were more likely to die from cardiovascular disease compared to people who ate across 12 to16 hours per day.

Time-restricted eating, a type of intermittent fasting, involves limiting the hours for eating to a specific number of hours each day, which may range from a 4- to 12-hour time window in 24 hours. Many people who follow a time-restricted eating diet follow a 16:8 eating schedule, where they eat all their foods in an 8-hour window and fast for the remaining 16 hours each day. Previous research has found that time-restricted eating improves several cardiometabolic health measures, for instance blood pressure, blood glucose, and cholesterol levels.

**Victor Wenze Zhong,** Ph.D., Professor & Chair for the Department of Epidemiology & Biostatistics at the Shanghai Jiao Tong University School of Medicine in China (and senior study author), said: "Restricting daily eating time to a short period, such as 8 hours per day, has gained popularity in recent years to lose weight and improve heart health. However, the long-term health effects of time-restricted eating, including risk of death from any cause or cardiovascular disease, are unknown."

In this study, researchers investigated the potential long-term health impact of following an 8-hour time-restricted eating plan. They reviewed information about dietary patterns for participants in the annual 2003 to 2018 National Health & Nutrition Examination Surveys (NHANES) by the U.S. Centers for Disease Control & Prevention (CDC) in comparison to data about people who died in the U.S., from 2003 through December 2019, in the CDC's National Death Index database.

The analysis found the following.

- People who followed a pattern of eating all their food across less than 8 hours per day had a 91% higher risk of death due to cardiovascular disease.
- The increased risk of cardiovascular death was also seen in people living with heart disease or cancer.
- Among people with existing cardiovascular disease, an eating duration of no less than 8 but less than 10 hours per day was also associated with a 66% higher risk of death from heart disease or stroke.
- Time-restricted eating did not reduce the overall risk of death from any cause.
- An eating duration of more than 16 hours per day was associated with a lower risk of cancer mortality among people with cancer.

Dr. Zhong remarked: "We were surprised to find that people who followed an 8-hour, time-restricted eating schedule were more likely to die from cardiovascular disease. Even though this type of diet has been popular due to its potential short-term benefits, our research clearly shows that, compared with a typical eating time range of 12 to 16 hours per day, a shorter eating

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# Heart Health News

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duration was not associated with living longer. It's crucial for patients, particularly those with existing heart conditions or cancer, to be aware of the association between an 8-hour eating window and increased risk of cardiovascular death. Our study's findings encourage a more cautious, personalized approach to dietary recommendations, ensuring that they are aligned with an individual's health status, and the latest scientific evidence. Although the study identified an association between an 8-hour eating window and cardiovascular death, this does not mean that time-restricted eating caused cardiovascular death."

Below are the study details and background.

- The study included approximately 20,000 adults in the U.S. with an average age of 49 years.
- Study participants were followed for a median length of 8 years and maximum length of 17 years.
- The study included data for NHANES participants who were at least 20 years old at enrollment, between 2003 to 2018, and had completed two 24-hour dietary recall questionnaires within the first year of enrollment.
- Approximately half of the participants self-identified as men, and half self-identified as women. 73.3% of the participants self-identified as non-Hispanic white adults, 11% self-identified as Hispanic adults, 8% self-identified as non-Hispanic Black adults, and 6.9% of adults self-identified as another racial category, including mixed-race adults and adults of other non-Hispanic races.

**Christopher D. Gardner,** Ph.D., FAHA, Rehnborg Farquhar Professor of Medicine at Stanford University in California and Writing Committee Chair of the AHA's 2023 scientific statement, *Popular Dietary Patterns: Alignment with AHA 2021 Dietary Guidance,* said: "Overall, this study suggests that time-restricted eating may have short-term benefits but long-term adverse effects. When the study is presented in its entirety, it will be interesting and helpful to learn more of the details of the analysis."

Future research may examine the biological mechanisms that underly the associations between a time-restricted eating schedule and adverse cardiovascular outcomes, and whether these findings are similar for people who live in other parts of the world.

Dr. Gardner concluded: "It will also be critical to see a comparison of demographics and baseline characteristics across the groups that were classified into the different time-restricted eating windows. For example, was the group with the shortest time-restricted eating window unique compared to people who followed other eating schedules, in terms of weight, stress, traditional cardiometabolic risk factors, or other factors associated with adverse cardiovascular outcomes? This additional information will help to better understand the potential independent contribution of the short time-restricted eating pattern reported in this interesting and provocative abstract."

### Daylight Saving Time May Impact Your Heart Health

On March 1, the American Heart Association (AHA) announced new study findings in which researchers have noticed a marked increase in heart attacks and strokes in the days following the spring Daylight Saving time change.

Daylight Saving time is the practice of setting the clocks an hour ahead of Standard time, to achieve longer evening daylight in the summer months. While gaining extra daylight may be a nice change, the transition could come with some health challenges.

According to a study of hospital admissions across the state of Michigan, there was a 24% increase in heart attacks on the Monday following the switch to Daylight Saving time (that is traditionally on an early Sunday around 2:00am). In a study from Finland, researchers found that the overall rate of ischemic stroke was 8% higher during the first 2 days after a Daylight Saving time transition. Other research has found that, in general, more serious heart attacks occur on Mondays than on any other day of the week, making the day after the time change even more worrisome.

**Maria Delgado-Lelievre,** M.D., AHA Volunteer Expert & Distinguished Hypertension Specialist at the University of Miami Leonard M. Miller School of Medicine in Florida, said: "We don't really know exactly why there is an increase in heart attacks and strokes during the change to Daylight Saving time. It is likely connected with the disruption to the body's internal clock, or its circadian rhythm. It is important to be aware of this increased risk, especially if you already have heart disease or other risk factors. Recognize the signs of a heart attack or stroke and call 9-1-1 if you or someone you're with experience any of those symptoms."

The AHA offers a few tips to get ahead of the time change before it arrives, as detailed below.

- **A month prior to the time change, go outside and get as much natural light as possible each day.** This can help adjust your body rhythm for the change to come.
- **Begin winding down a little earlier in the evenings.** While you can never make up lost sleep, going into the time change well-rested can help.

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- **Don't compensate with extra caffeine.** It may feel like an extra coffee or two can help you through the midday slump, but too much caffeine is not heart healthy.

Dr. Delgado-Lelievre explained: "We know that the amount and the quality of sleep a person gets at any time of the year is essential to good health. That's why the AHA has added sleep to our Life's Essential 8™, which is our equation of 4 health factors and 4 health behaviors that are needed for good cardiovascular health. In addition to increasing the risk for cardiovascular conditions like heart attack and stroke, lack of sleep may also put people at risk of things like depression, cognitive decline, and obesity."

Several recent studies have highlighted how sleep impacts your heart health, as listed below. The first few were from studies that were also published in the AHA's two publications: *Journal* or *Hypertension;* and the last is noted as being an abstract presented at one of AHA's annual meetings.

- Variations in sleep duration of more than 2 hours a night within the same week were tied to developing hardened arteries, known as atherosclerosis.
- The link between excess weight and higher blood pressure in adolescents was stronger among those who also had irregular sleep patterns. Irregular sleep patterns contributed to elevated blood pressure in teens who had more visceral fat, which is excess weight in the belly/abdominal area.
- About 1 in 4 women after menopause may develop irregular heart rhythms (known as atrial fibrillation, or A-fib), with stressful life events and poor sleep being their leading contributing factors.
- More than one-third of children in the U.S. did not get the amount of sleep that is recommended (taken from an abstract presented at the AHA's 2023 Scientific Sessions meeting).

The AHA's Life's Essential 8 recommends the following ideal levels of sleep for adults, teens, and children.

- 7 to 9 hours daily for adults.
- 8 to 10 hours daily for ages 13 to 18 years.
- 9 to 12 hours daily for ages 6 to12 years.
- 10 to 16 hours daily for ages 5 and younger.

Dr. Delgado-Lelievre noted: "More than 1 in 3 adults don't get the recommended amount of sleep. It's important to maintain a healthy sleeping pattern all year long for best heart health and many other health benefits. Know there are specific steps you can take to set yourself up for a good night's rest."

These healthy sleep pattern recommendations are detailed below.

- **Do not hit snooze.** Sleeping past your alarm can make you groggier in the morning. Try putting your alarm clock across the room so you must physically get out of bed to turn it off.
- **Prioritize exposure to natural light.** Maximize exposure to natural light during the day to regulate your body's internal clock and prepare for a restful night. Try going for a walk when you wake up, to promote physical activity while getting natural sunlight.
- **Eat a healthy, balanced diet.** Enjoy a heart-healthy diet with plenty of fiber-rich vegetables, fruits, legumes, and whole grains and balance your calories throughout the day. When you get more calories late at night, sleep may be less peaceful.
- **Watch what you drink.** Drinking too many sugary, caffeinated, or alcoholic beverages may lead to more disruptions during the night.
- **Limit afternoon naps.** Avoid taking long naps during the day because they can disrupt your sleep patterns and make it harder to achieve restful sleep at night. Instead, focus on maintaining consistent sleep patterns to support good overall sleep quality.
- **Limit technology use in the evening.** The blue light of most electronic devices can interfere with your circadian rhythm and melatonin production, which helps you sleep. Create a conducive sleep environment by keeping electronic devices out of the bedroom. Aim to disconnect from screens at least one hour before bedtime to reduce exposure to blue light and promote better sleep quality.
- **Create a relaxing bedtime routine.** Engage in calming activities before bed, such as reading a book, journaling, taking a warm bath, or practicing relaxation exercises like deep breathing or meditation. Relaxing activities can help ease into a restful night's sleep.

Dr. Delgado-Lelievre concluded: "Making small changes in your daily habits can make a big difference in your sleep quality and overall health. Instead of turning on the TV to help you fall asleep, try reading a book or journaling about your day. Putting your phone in another room can also prevent the temptation to scroll in bed. Making these small changes now can help you prepare for the next Daylight Saving time change, and ensure your sleep patterns are strong and more likely to remain consistent all year long."

### Half Of Adults Still Unaware Heart Disease Is Leading Cause Of Death

On January 24, the American Heart Association (AHA) announced that according to a recent Harris Poll survey conducted on behalf of the AHA in November 2023, more than half of Americans (51%) still don't know that heart disease is the leading cause of death in the country.

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Yet, heart disease has now been the number 1 killer for more than a century, according to the "2024 Heart Disease & Stroke Statistics: A Report of U.S. & Global Data" by the AHA (www.heart.org/en/about-us/heart-and-stroke-association-statistics).

**Joseph C. Wu,** M.D., Ph.D., FAHA, Volunteer President of the AHA, Director of the Stanford Cardiovascular Institute and Simon H. Stertzer Professor of Medicine & Radiology at Stanford School of Medicine in California, stated: "Heart disease has now been the leading cause of death in this country for 100 years straight, since 1921, according to the U.S. Centers for Disease Control & Prevention (CDC). Heart disease along with stroke, which is the fifth leading cause of death, claims more lives in the U.S. than all forms of cancer and chronic lower respiratory disease combined, based on the most recent data available. So, the results of this survey, finding that most people do not know the significant impact of heart disease, is discouraging and even a bit frightening."

In the survey, only 49% of people named heart disease as the leading cause of death; 16% said they did not know the leading cause; and 18% listed cancer as the top cause of death of people in the United States.

Dr. Wu cautioned that this lack of knowledge and awareness is potentially deadly, as this year's statistical update reports that half of all people in the U.S. (48.6%) have some type of cardiovascular disease (CVD), including coronary heart disease, heart failure, stroke and, most notably, high blood pressure.

According to the 2024 statistical update, 46.7% of U.S. adults have high blood pressure. Yet, 38% of those with high blood pressure are unaware that they have it. In the past 10 years, the age-adjusted death rate from high blood pressure increased 65.6% and the actual number of deaths rose 91.2%.

Dr. Wu said: "High blood pressure is a leading risk factor for heart disease and stroke, and yet with proper treatment and management it can be controlled and your risk for CVD can be greatly reduced. The first step toward reducing any risk factor for CVD is awareness. When the AHA was founded one hundred years ago, heart disease was considered a death sentence. Little was known about what caused it and even less about how to care for people living with and dying from it. The knowledge we continue to gain through research and data such as that reported in this statistical update is helping make significant inroads. Although too many people still die each year, many are living longer, more productive lives while managing their CVD and risk factors."

Several highlights in the fight against CVD published in a special foreword of this year's statistical update are detailed below.

- Since 1950, death rates from CVD have declined 60%; the rates have fluctuated over the years and have recently trended upward. Dr. Wu notes this trend aligns with increases in the prevalence of risk factors that cause heart disease and stroke, such as high blood pressure and obesity.
- The number of people in the U.S. dying of a heart attack each year has dropped from 1 in 2 in the 1950s to now 1 in 8.5. Dr. Wu noted this is due in part to improved diagnosis and treatment options.
- Stroke was first ranked as the third leading cause of death in 1938. However, stroke mortality has been on the decline since the early 20th century and in the U.S., now ranks as the fifth leading cause of death. Aggressive evidence-based public health programs and clinical interventions have played a key role in reducing the number of stroke deaths.
- Cigarette smoking has fallen dramatically from greater than 40% of U.S. adults smoking in the mid-1960s to about 11% today. The AHA has led the charge in this decline, supporting increased public awareness about the dangers of nicotine and tobacco use and policy initiatives that have placed legal restrictions on smoking in public spaces and placed higher taxes on cigarette products.

**Seth S. Martin,** M.D., M.H.S., FAHA, Volunteer Chair of the AHA Statistical Update Writing Committee and Professor of Medicine & Cardiologist at Johns Hopkins School of Medicine in Baltimore, Maryland, said: "Identifying trends like this is a key reason why we compile the AHA's statistical update, which has been released annually since 1927. Although the research and statistics included in each year's report illustrate the most recent data available, the historical data pulled from the collective work over the years is especially invaluable. As it has evolved over the years, the report has become a preeminent resource in identifying the overall impact of CVD, including who is most affected, where it is most prevalent and what factors may increase the risk of it. This type of information is crucial to the development of awareness initiatives and policy strategies and provides a road map for cardiovascular research priorities."

Dr. Martin noted that last year's statistical update identified a concerning increase in cardiovascular related deaths–the largest single-year increase since 2015–which may have reflected the first year of the COVID-19 pandemic. The following data trends on cardiovascular deaths reported in this year's update also show an increase, however it appears lower in magnitude.

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- The overall number of cardiovascular related deaths was 931,578, an increase of less than 3,000 from the 928,741 deaths reported last year. Last year, the number of deaths increased more than 54,000 over the previous year.
- Cardiovascular deaths include deaths from coronary heart disease (40.3%), stroke (17.5%), other minor CVD causes combined (17.1%), high blood pressure (13.4%), heart failure (9.1%), and diseases of the arteries (2.6%).
- The age-adjusted death rate from CVD increased to 233.3 per 100,000, up 4.0% from 224.4 per 100,000 reported last year, whereas the rate had increased 4.6% in the previous year. Last year's increase was the first increase in age-adjusted death rates seen in many years.

Dr. Martin explained: "While the long-term impact of the pandemic is yet to be seen, we're cautiously optimistic that the trends from this year's update indicate a slowdown in the striking effects we initially saw. There is still much work to be done in the overall fight against CVD. Recognizing that most people do not realize heart disease is the leading cause of death in the U.S., it's imperative that we share the data from our statistics update even more broadly to increase this awareness."

Additional key facts from the 2024 report are as follows, all based on data as related to people in the United States.

- There are 2,552 deaths from total CVD each day, based on 2021 data.
- On average, someone dies of CVD every 34 seconds.
- There are about 1,905 deaths from heart disease each day, including heart attacks.
- About every 40 seconds, someone will have a heart attack.
- Each year there are about 605,000 new heart attacks and 200,000 recurrent attacks. Of these, it is estimated that 170,000 are silent, without significant symptoms.
- The average age at first heart attack is 65.6 years for males and 72.0 years for females.
- There are about 446 deaths from stroke each day, based on 2021 data.
- On average, someone dies of a stroke every 3.14 minutes.
- Each year, 795,000 experience a new or recurrent stroke.
- Approximately 610,000 of these are first attacks and 185,000 are recurrent attacks.
- Stroke accounts for about 1 of every 21 deaths.
- In 2021, sudden cardiac arrest attributed to 20,114 deaths.
- On average, there are about 55 deaths each day from sudden cardiac arrest.
- According to 2022 data, most adult out-of-hospital cardiac arrests (OHCA) occur at a home or a residence (72.1%). Public settings (17.3%) and nursing homes (10.6%) were the second and third most common locations.
- According to 2022 data for adult OHCA only, survival to hospital discharge was 9.3% for all EMS-treated non-traumatic OHCA cardiac arrests. Bystander witnessed adult arrests had a 14.0% survival to hospital discharge and 9-1-1 responder witnessed arrests had a 17.0% survival to hospital discharge.

Some key global statistics from the new report include the following.

- In 2019, 27% of the world's deaths were caused by CVD, making it the predominant cause of death globally.
- CVD accounted for approximately 19.91 million global deaths in 2021.
- Worldwide, tobacco contributed to an estimated 7.43 million deaths in 2021.
- Worldwide, high body mass index was attributed to 3.69 million deaths in 2021, an increase of 46.7% compared with 2010.
- In 2021, an estimated 1.70 million deaths were attributed to diabetes globally.

Dr. Wu concluded: "I cannot stress enough how important it is to fully recognize just how much all cardiovascular diseases, including heart disease and stroke, impact each of us as individuals and communities. If you do not have heart disease yourself, chances are you know someone who does, a family member or other loved one. Arm yourself with knowledge that can help you reduce your risk of becoming a future statistic."

### Now In 100th Year, AHA Sets New Goals To Improve Emergency Cardiovascular Care

On January 22, the American Heart Association (AHA) announced the release of a new scientific statement, which sets impact goals in order to double the rate of survivorship in people who experience a cardiac arrest by 2030.

According to the "AHA Emergency Cardiovascular Care 2030 Impact Goals & Call to Action to Improve Cardiac Arrest Outcomes," only 10% of people who experience a cardiac arrest survive. Therefore new challenge goals have been outlined with the intention of doubling survivorship to 20% in the next 10 years.

The statement details how these goals for the nation can be achieved by increasing the rate of bystander cardiopulmonary resuscitation (CPR) to more than 50% and increasing the frequency of defibrillation (AED use) for out-of-hospital cardiac arrest before emergency services arrive; survival after cardiac arrest whether at home or in the hospital, and neurologically intact survival (surviving with proper brain function).

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Equity-focused goals are also key to improving cardiac arrest survival outcomes with a specific focus on racial/ethnic and other historically marginalized groups and communities with low socioeconomic status.

The volunteer expert writing committee identifies clinical goals every 10 years that are aligned with the AHA's broader mission while seeking to provide guidance for scientists, healthcare professionals, the public, policymakers, and others to focus on improving outcomes from cardiac arrest. This new, bold goal, announced during the AHA's centennial year with 2024 marking its 100th Anniversary, highlights its focus on saving and improving lives.

**Raina M. Merchant,** M.D., M.S.H.P., FAHA, Volunteer Chair of the AHA Statement Writing Committee and Professor of Emergency Medicine at the University of Pennsylvania's Perelman School of Medicine in Philadelphia, said: "We hope these goals will serve as an aspirational and achievable road map for improved heart health and better survival rates in all communities and for all people. Achieving them will truly take a collaboration among healthcare professionals, first responders and the public and will require supporting registries, such as AHA's Get With the Guidelines® and more, to help with tracking and reporting about the many factors that impact cardiac arrest incidence, treatment, and outcomes."

Currently, 90% of people who experience cardiac arrest outside of a hospital die, in part because they do not receive CPR more than half of the time. To save more lives from the approximately 350,000 cardiac arrests that occur outside of the hospital every year, increasing the number of people who respond to cardiac arrest by calling 911, delivering high-quality CPR, and getting and using an AED as soon as it is available are crucial to survival outcomes.

Black or Hispanic adults who experience cardiac arrest outside a hospital setting are substantially less likely to receive lifesaving care from a bystander. The AHA is working to change this by improving access to lifesaving CPR training in these communities.

The AHA's focus on CPR training and education has already shown improvement in bystander willingness to provide lifesaving care. In a 2023 consumer survey, over half of the participants said they would perform either CPR or Hands-Only CPR and that their confidence level in performing CPR has improved from 2021. Immediate CPR and defibrillation are key to doubling the survival rate of cardiac arrest by 2030.

### Childhood Stress Linked To Higher Risk Of High Blood Pressure, Obesity, & Diabetes As Adults

On January 17, the American Heart Association (AHA) announced findings from a new study, which found young adults who reported higher stress during their teenage years to adulthood were more likely to have high blood pressure, obesity, and other cardiometabolic risk factors than their peers who reported less stress.

Cardiometabolic risk factors often occur together and are a significant cause of cardiovascular disease. These include obesity, Type 2 diabetes or prediabetes, high cholesterol, and high blood pressure, researchers noted.

**Fangqi Guo,** Ph.D., Postdoctoral Research Fellow at Keck School of Medicine at the University of Southern California in Los Angeles (and study author), explained: "Understanding the effects of perceived stress starting in childhood is important for preventing, lessening, or managing higher cardiometabolic risk factors in young adults. Our findings suggest that perceived stress patterns over time have a far-reaching effect on various cardiometabolic measures including fat distribution, vascular health, and obesity. This could highlight the importance of stress management as early as in adolescence as a health protective behavior."

In 2020, cardiometabolic diseases, including cardiovascular diseases and Type 2 diabetes, were the most prevalent chronic health conditions and collectively accounted for nearly a quarter of all deaths in the U.S., according to AHA statistics. In 2023, the AHA noted the strong connections among cardiovascular disease, kidney disease, Type 2 diabetes, and obesity, and suggested redefining cardiovascular risk, prevention, and management.

Childhood adversities affect cardiometabolic health across the life course, and interventions that improve early exposures may be more appropriate than interventions for cardiovascular disease risk factor effects later in life. In recent decades, researchers have found that perceived stress is a risk factor for cardiometabolic health conditions.

For this study, researchers analyzed health information from the Southern California Children's Health Study. Participants had enrolled in the study as children along with their parents, then participated in follow-up assessments as adolescents (average age 13) and as young adults (average age 24).

At each stage, stress was measured with a 4-item Perceived Stress Scale, which is a questionnaire about feelings and thoughts during the last month. Study participants were categorized into 4 risk-based groups: 1) Consistently high stress over time; 2) Decreasing stress over time; 3) Increasing stress over time; and 4) Consistently low stress over time.

To evaluate cardiometabolic risk in young

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adulthood, Dr. Guo and colleagues used measures of carotid artery intima-media thickness (measures neck artery thickness); systolic (top number) and diastolic (bottom number) blood pressure; weight, percentage of body fat, and fat distribution; and hemoglobin A1C. Hemoglobin A1C gauges blood sugar over time; increased thickness of the neck artery's inner layers suggests blood may not be flowing smoothly; and more fat around the abdomen is associated with a higher risk of cardiovascular diseases and/or Type 2 diabetes.

The participants included 276 people from Southern California communities participating in the Southern California Children's Health Study. Participants enrolled as children from 2003 to 2014, and took part in follow-up health assessments as adults from 2018 to 2021. First researchers investigated perceived stress reported by participants' parents during childhood (average age of about 6 years). After that it was reported by participants themselves, in adolescence (average age about 13 years) and then again in young adulthood (average age nearly 24 years). About 56% of participants were girls/women; 62% identified as White; 47% identified as Hispanic; 5% as Asian; 1% as either Black or Native American; and 13% were classified as "other."

The analysis found the following.

- Consistently high perceived stress from adolescence through adulthood was associated with greater risk for cardiometabolic diseases in young adulthood. If individuals experienced greater levels of stress from their teenage years into adulthood, they were more likely to have worse vascular health, higher total body fat, more fat around the belly, and higher risk of obesity compared to those who felt less stressed over time.
- In general, higher perceived stress levels were also associated with higher risk for cardiometabolic health conditions. For example, adults who experience higher levels of stress tended to have worse vascular health and higher systolic and diastolic blood pressure.

Dr. Guo concluded: "Although we assumed that perceived stress patterns should have some association with cardiometabolic measures, we did not expect such consistent patterns across various risk factors. Healthcare professionals should consider using the Perceived Stress Scale to evaluate individuals' stress levels during clinic visits. This way, those with higher stress levels can be identified and receive treatment earlier."

### Heart Disease Deaths Linked With Substance Use Rose 4% Between 1999 To 2019

On January 10, the American Heart Association (AHA) announced according to newly published research, cardiovascular disease deaths involving substance use rose an average of 4% per year from 1999 to 2019, despite a drop in overall cardiovascular disease deaths.

**Dmitry Abramov,** M.D., Cardiologist & Associate Professor of Medicine at Loma Linda University Health in California (and senior study author), said: "The study results were generally consistent with what we see in our clinic while caring for patients with cardiovascular disease. Although alcohol and opioids were the substances most associated with cardiovascular deaths, the increases in cardiovascular deaths related to stimulants (predominantly amphetamines) during the study period were particularly prominent. This highlights both the ongoing risk of common substances, including alcohol and opioids, and demonstrates the need to tackle amphetamines as a substance whose contribution to cardiovascular disease (CVD) deaths is growing more rapidly."

Researchers reviewed publicly available data from the Wide-Ranging Online Data for Epidemiologic Research (WONDER) database by the U.S. Centers for Disease Control & Prevention (CDC), to investigate death trends related to substance use from 1999 to 2019. The data included 636,572 substance use-related cardiovascular deaths. Of these, 75.6% were among men, and 70.6% of the individuals were non-Hispanic White people. Smoking/tobacco use was *not* included as a form of substance use in this study. The analysis found the following.

- The overall rate of substance use-related cardiovascular deaths increased from 9.9 per 100,000 population in 1999 to 21.4 per 100,000 population in 2019, representing an average annual increase of 4%.
- Increases in substance use-related average annual percent changes were noted across all subgroups and were pronounced among women (4.8%); American Indian or Alaskan individuals (5.4%); younger adults, ages 25 to 59 (5.3%); people living in rural areas (5%); people who used cannabis (12.7%); and psychostimulants (16.8%).
- 65% of cardiovascular disease deaths were related to alcohol, followed by opioids (13.7%), cocaine (9.8%), stimulants (6.5%), sedatives (4.1%), and cannabis (0.5%).
- The highest rate of change was noted among adults ages 25 to 39 (5.3%), followed by adults ages 55 to 69 (4.9%).
- The age-adjusted death rate was 15.2 per 100,000 in adults living in non-metropolitan/rural areas, 22.5 per 100,000 in men; and 37.7 per 100,000 in American Indian or Alaska Native adults.

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Dr. Abramov noted: "We were surprised to see significant increases among those ages 25 to 39 compared to other age groups, and among people in certain racial and ethnic groups including White adults and American Indian/Alaska Native adults. Identifying high-risk groups is crucial to prioritize preventive measures to reduce substance use-related CVD deaths. In addition, while the rates of cardiovascular disease mortality related to substance use were higher in men than women, women demonstrated larger increases during the study period. Data from prior studies have found notable increases in substance use among women over the last 20 years, and women may face unique societal risks that may contribute to the increases noted in our study. These sex-based differences, in addition to the differences by race and ethnicity, age, and living in an urban or rural community, require additional research. We would like to see additional public health efforts to support comprehensive evalution and management of substance use in the U.S. that includes clinician and patient education, as well as attention to socioeconomic factors that contribute to substance use. Such efforts are critical in reversing the trends in CVD deaths associated with substance use and will hopefully lead to further reduction in the overall burden of heart disease and stroke."

### Heart Stenting Study Shows It Relieved Chest Pain & Improved Exercise Capacity

On November 11, 2023, the American Heart Association (AHA) announced results of a new study confirming that stenting, also called percutaneous coronary intervention (PCI), relieves stable chest pain and improves exercise capacity among patients taking little or no chest pain medication.

Medication is proven to treat pain caused by reduced blood flow to the heart triggered by exertion, exposure to cold, emotional stress, and other events, commonly referred to as stable angina or stable chest pain. When medication is insufficient, stenting procedures are recommended.

The only previous trial examining whether stenting relieves chest pain, published in 2017, surprisingly showed that stenting did not improve exercise tolerance or chest pain any more than a placebo procedure. It proved the feasibility of conducting placebo-controlled trials of established interventional procedures and made it possible to design subsequent research applied to a wider population of patients and clinical practice.

**Rasha Al-Lamee,** M.B.B.S., Ph.D., Clinical Academic Interventional Cardiology Consultant and Clinical Reader (equivalent to Associate Professor) at Imperial College Healthcare NHS Trust and British Heart Foundation Intermediate Research Fellow in London, England, said: "However, it is possible that the effect of stenting in the previous study was diminished by high levels of guideline-directed background, antianginal medication, which are difficult to achieve in clinical practice. For the new study, we calculated an 'angina symptom score' daily for each participant based mainly on how much chest pain they experienced and their need for antianginal medication. We found that stents improved symptoms compared to the placebo procedure."

The study included 79% male participants, and the average age was 64 years. Study participants also had other health conditions, including hypertension (63%), Type 2 diabetes (28%), and high cholesterol (72%). There were no deaths in the trial, although heart attacks occurred in 4 patients in the stenting group and 6 patients in the placebo group. The study revealed the following.

- Patients who had stents were 3-times more likely to be free from angina at the end of the trial compared to patients who had the placebo procedure.
- Stenting improved the angina symptom score, with follow-up scores of 2.9 in the PCI group and 5.6 in the placebo group.
- Exercise time increased by 60 seconds more among patients who received stenting compared to those who received the placebo.
- The effect of stenting was immediate as well as sustained over the 12-weeks of follow-up.

Dr. Al-Lamee explained: "We expected that PCI would be more effective than a placebo procedure in patients taking little or no chest pain medication, and indeed, the results proved our hypothesis was correct. Going forward, patients and medical teams have a choice of two pathways for chest pain relief: chest pain medication or PCI. The key finding of this trial is that it is the first therapy initiated that seems to have the maximum effect. Although PCI is neither risk-free nor cost-free, its use as an upfront procedure can now be considered evidence based. The original and current trials together suggest the American and European guidelines for stable coronary artery disease may require updating. Perhaps restricting stenting to patients with inadequate response to chest pain medications may inadvertently be selecting the group of patients with the least to gain."

However, Dr Al-Lamee noted there are several reasons the findings should be interpreted cautiously, as listed below.

- PCI only provided a 60-second improvement in exercise time. This is a smaller effect than

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many cardiologists would have believed from unblinded data, and is also similar to the effect of one full-dose of an anti-anginal medication.

- PCI is not universally effective. In this study, 59% of patients who received stents continued to experience chest pain even after a successful procedure and near-normalization of the blood supply to the heart.

Dr. Al-Lamee concluded: "I hope that these study trials will be used together to give patients and medical teams the choice of 2 treatment strategies with similar levels of benefit. They each have their own benefits, risks, and limitations that should form part of the decision-making process. Importantly, the first therapy administered, antianginal medication or PCI as an antianginal procedure, appears to deliver most of the available symptomatic response."

### Red Blood Cell Transfusions May Improve Outcomes In Heart Attack Patients With Anemia

On November 11, 2023, the American Heart Association (AHA) announced a new research study suggests there may be benefits to an expanded red blood cell transfusion approach for hospitalized heart attack patients with anemia.

Previous studies on transfusion strategies for people hospitalized with heart attack have yielded conflicting results. Doctors thought giving more blood transfusions would increase the amount of oxygen for the heart and improve outcomes. However, giving more blood transfusions may increase the risk of fluid overload and rare infections. This uncertainty in when to transfuse heart attack patients led to this clinical trial.

**Jeffrey L. Carson,** M.D., Provost & Professor of Medicine at Rutgers Robert Wood Johnson Medical School and Richard C. Reynolds Chair of General Internal Medicine in New Brunswick, New Jersey (and study author), noted: "Low red blood count or anemia is common among people hospitalized with heart attack. We believe our results suggest a more liberal transfusion approach may be beneficial for these patients without significant risk."

In the clinical trial, anemia was defined as a hemoglobin concentration of less than 10Gm/dL. Participants were randomly allocated to a restrictive or a liberal transfusion strategy. In the liberal transfusion strategy, red blood cells were transfused to maintain the hemoglobin at or above 10Gm/dL through hospital discharge or 30 days. In the restrictive transfusion strategy, transfusion was permitted only when the hemoglobin concentration was less than 8Gm/dL and strongly recommended when the hemoglobin concentration was less than 7Gm/dL or for cardiac symptoms not controlled with medications.

The trial enrolled 3,506 participants from 144 hospitals in the United States, Canada, France, Brazil, New Zealand, and Australia, between April 2017 and April 2023. All participants (average age 72 years with 45% women and 55% men) had heart attack and hemoglobin concentration levels less than 10Gm/dL. Normal hemoglobin concentration is 12Gm/dL to 13Gm/dL. Many participants also had other health conditions, including a history of heart attack (33%), heart failure (30%), diabetes (54%), and kidney disease (46%).

The primary trial endpoint was the composite of all-cause death and recurrent heart attack through 30 days following trial randomization. Secondary outcomes included individual components of the primary outcome, and the composite of all-cause death, heart attack, unscheduled coronary revascularization due to recurrent heart symptoms, or readmission to the hospital for a heart-related diagnosis within 30 days. Other outcomes included heart failure and infection. Cause of death were cardiac, non-cardiac, or undetermined.

The study's analysis found the following.

- 295 (16.9%) of the 1,749 participants in the restrictive transfusion trial pool experienced a recurrent heart attack or death compared to 255 (14.5%) among 1,755 participants in the liberal transfusion pool.
- Cardiac death was more common in people treated with a restrictive transfusion strategy (5.5%) compared to death among those treated in the liberal strategy (3.2%).
- Heart failure and other 30-day clinical outcomes were similar in both groups, which suggested there are no undue risks to more liberal transfusions.

Dr. Carson explained: "The study results require a nuanced interpretation. While the trial did not produce a statistically significant difference between the two transfusion strategies for the primary outcome, the results suggest the possibility of liberal transfusion benefits without undue risk. The study results suggest a liberal transfusion strategy may be the most prudent approach for patients with heart attack and anemia. Future research is needed to further resolve the controversy around transfusion decisions for people with anemia and heart attack."

### Reducing Sodium Intake Lowered Blood Pressure In As Little As 1 Week

On November 11, 2023, the American Heart Association (AHA) announced results of a new study, which revealed that reducing daily sodium intake by about 4,000mg/day significantly lowered systolic blood pressure in more than 70% of

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# Outstanding Buyer Nominee - Jemma Carrillo

***What is the nominee's name, job title, facility name, and location?*** **Jemma Carrillo**, Pharmacy Inventory Control Specialist, Torrance Memorial Medical Center, Torrance, California.

***As a nominating third party, please provide your own name, title, facility, and relationship to the nominee.*** **Diana Tomicic**, Pharmacy Technician Supervisor at Torrance Memorial Medical Center. I am Jemma's colleague.

***Is the nominee certified, licensed, and/or registered, as a Pharmacy Technician in their state?*** Yes, the nominee is both a Certified & Licensed Tech.

***Is the nominee a current NPPA member, and will be current through this August?*** Yes, the nominee is a current NPPA member and will be through this August.

***What is the number of beds at the nominee's facility, and what type of facility is it? (Teaching vs. community, rural vs. urban, etc.)*** 401-bed community facility.

***Approximately how many dollars per year of pharmaceutical-related expenditures does the nominee purchase or supervise the purchasing of at the nominee's facility?*** $28 million.

***What is the average dollar amount of pharmacy inventory the nominee controls each year?*** $2.4 million.

***What is the nominee's/Pharmacy Department's current Inventory "Turns"?*** 12.

***How long has the nominee been a Pharmacy Buyer?*** Jemma has been a Buyer for 3 years and 6 months.

***What are the nominee's primary responsibilities as a Pharmacy Buyer and otherwise?***

- Minimizing waste and preventing overstock situations
- Maintaining optimal inventory levels.
- Implementing cost-saving measures.
- Monitoring expenditures to stay within budgetary constraints.
- Managing drug shortages.
- Responding swiftly to unforeseen supply chain disruptions.

***What may be unique or challenging about the nominee's facility?*** Torrance Memorial Medical Center is a mid-sized community hospital dedicated to serving the needs of its local population. This presents unique challenges. Our buyer frequently navigates the complexities of procuring hard-to-acquire medications.

***List any accomplishments or projects the nominee instituted that have either saved money for their department/facility, or helped to make their job or the department/facility run more efficiently.***

Our Buyer is an integral member of our Value Added Team (VAT), contributing significantly to managing budgets and reducing costs. VAT comprises our pharmacy buyer and managers, contract analysts, and the supply chain and accounting teams. Together, we review drug expenditures to identify potential savings in our annual drug budget. Jemma excels at balancing adequate inventory for patient care with maintaining budgetary constraints. She closely monitors inventory turnover, ensuring medications are used efficiently and do not expire. Jemma consistently demonstrates exceptional skill and dedication in her role, expertly balancing inventory management with budgetary constraints to ensure optimal patient care. Her keen eye for detail and proactive approach have made a significant impact on our pharmacy operations. Her professionalism, commitment, and outstanding performance make her a true asset to our department and a deserving recipient of this prestigious award.

***How has the nominee's job changed over the years?*** Over the years, our Buyer has increasingly focused on addressing drug shortages and managing inventory procurement.

***What does the nominee like about their job?*** Jemma enjoys the challenge of procuring hard-to-get medications, engaging with drug representatives, and maintaining a well-organized inventory.

***What does the nominee dislike about their job?*** Jemma would prefer to avoid spending her time constantly monitoring inventory counts.

***What advice would the nominee have for drug company vendor representatives?*** Keep good relationships, understand the facility's needs, and be proactive.

***What specific challenges does the nominee face on the job?*** Jemma faces several specific challenges, including the following:

- Managing drug shortages—constantly navigating the complexities of drug shortages and finding alternative sources to ensure continuous supply.
- Balancing budget constraints—carefully managing budget constraints while still procuring high-quality medications at the best possible prices.
- Inventory optimization—maintaining optimal inventory levels to prevent both overstocking and stockouts, while also minimizing medication expiration and waste.

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# Heart Health News

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adults in as little as one week compared to their usual diet.

**Deepak K. Gupta,** M.D., M.S.C.I., FAHA, Associate Professor of Medicine and Director of the Vanderbilt Translational & Clinical Cardiovascular Research Center at Vanderbilt University Medical Center in Nashville, Tennessee, said: "High blood pressure is the most common chronic disease condition in the world, and for the majority of adults, dietary sodium intake influences blood pressure. However, dietary sodium recommendations are debated in part due to the variability in blood pressure response to sodium consumption from food."

Researchers measured participants' blood pressure while on their usual diets, then conducted a randomized trial in these same participants to understand how variation in dietary sodium between higher- and lower-sodium intake may relate to changes in blood pressure.

The study included more than 200 adults, ages 50 to 75 years, from the Coronary Artery Risk Development in Young Adults (CARDIA) study as well as other individuals. Participants were randomized to either a high-sodium diet with 2,200mg of sodium added to their usual daily diet, or a low-sodium diet with a total of 500mg sodium daily for 1 week. Participants then switched to the opposite diet for 1 week. Participants' blood pressure was measured over a 24-hour period on the last day of each diet.

The results found that 1 week of the low-sodium diet significantly lowered systolic blood pressure in nearly 75% of adults. The median systolic blood pressure measurements were 125mm, 126mm, and 119mm Hg for the usual, high- and low-sodium diets, respectively.

Systolic blood pressure was significantly lowered by 7mm to 8mm Hg for participants while following the low-sodium diet compared with those in the high-sodium group, and by 6mm Hg compared with participants following their usual diet. These reductions in systolic blood pressure are comparable to the reductions attained with a common, first-line medication for hypertension.

The usual diet for most individuals was already very high in sodium, at approximately 4,500mg/day. Participants' systolic blood pressure was not significantly greater with the high-sodium diet compared with usual diet. In contrast, returning to a high-sodium diet did raise blood pressure when starting from the low-sodium reference point.

Dr. Gupta explained: "These results indicate that lowering blood pressure through dietary sodium reduction can be achieved safely and rapidly within one week. Our study also supports the AHA's position that consuming excess sodium beyond recommended levels is associated with increasing blood pressure."

Additionally, the effect of reduction in dietary sodium on blood pressure was consistent across individuals with normal blood pressure, treated high blood pressure, and untreated high blood pressure.

In contrast to several of the largest prior studies examining the effect of dietary sodium

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# Outstanding Buyer, J. Carrillo

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***How has the nominee's NPPA membership helped them in their job and/or personally?***

Being part of the larger NPPA group has validated Jemma's role and duties as a Buyer. She has become more confident in navigating the many challenges of purchasing.

***Has the nominee ever attended an NPPA Conference? If so, how did that help in their job after the event? If not, what prevented them from attending?*** Yes, attending the NPPA Conference connects Jemma to other like-minded people who work in similar facilities. She attends when possible.

***If the nominee were one of the top-2 placing awardees for this program, would they be able to attend the upcoming NPPA Conference?*** Yes.

***Does the nominee belong to any other professional organizations besides NPPA? If so, are they involved with any of them beyond being a member?*** None that I know of.

***List any other qualifications the nominee may have for this award, such as being recognized by their facility, having an article published, organizing buyer meetings, public speaking, volunteer work, etc.***

Jemma assumed the Pharmacy Buyer position at Torrance Memorial Medical Center during the height of the pandemic. She navigated COVID drug shortages, odd workflow changes, and new pandemic-era restrictions. Her introduction to the Buyer world began with bang!

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on blood pressure, the trial included individuals taking medications for high-blood pressure as well as people with diabetes (Type 1 or Type 2 not collected). At the start of the study, about one-quarter of the 213 participants had normal blood pressure, 20% had controlled high blood pressure, 31% had uncontrolled high blood pressure, and the remaining 25% had untreated high blood pressure. Approximately 1 in 5 participants had diabetes. 73% of participants were from the CARDIA study. Other participants were adults in Birmingham, Alabama and Chicago, Illinois. Participants were ages 50 to 75 years, 65% were women, and 64% were Black adults.

The low-salt diet included food and drinks provided by the researchers and daily meal plans. Sample breakfasts included oatmeal, Greek yogurt, and grapes; sample lunches included fruit, a bag of chips, and either a chicken salad, lentil soup, or peanut butter and jelly sandwich; and sample dinners included fruit, a bottle of 1% low-fat milk, and either a low-sodium frozen burrito, low-sodium frozen vegetable lasagna, or a low-sodium rice and vegetable entree.

Participants on the high-sodium diet added 2,200mg of sodium to their regular daily diet by consuming 2 chicken bouillon packets daily, with 1,100mg of sodium each, as provided by the researchers. The median estimated total daily sodium intake for people on the high-sodium diet was 5,000mg/day. People on the low-sodium diet had a median, 24-hour urine sodium level of approximately 1,300mg, suggesting that some individuals consumed sodium outside of the food and drink provided.

The U.S. Department of Agriculture's *Dietary Guidelines for Americans 2020-2025* recommends adults should consume less than 2,300mg of sodium daily; however, it is estimated that adults in the U.S. typically consume about 50% more sodium, or about 3,400mg/day. The AHA recommends no more than 2,300mg of sodium/day and moving toward an ideal limit of no more than 1,500mg/day for most adults.

### Coronary Heart Disease Before Age 45 May Increase Risk Of Dementia Later In Life

On November 10, 2023, the American Heart Association (AHA) announced results of new research, which found that adults diagnosed with coronary heart disease–especially before the age of 45, may be at increased risk of developing dementia, Alzheimer's disease, and vascular dementia later in life.

The researchers assessed the potential relationship between age at coronary heart disease (CHD) onset and the development of dementia by analyzing health data from the U.K. Biobank. The U.K. Biobank is a large, biomedical database and research resource with health records of about 500,000 adults, enrolled from 2006 until 2010, who live in the U.K. and received healthcare through the U.K.'s National Health Service. The researchers accessed the data in May 2022 and analyzed it from October to December 2022.

Among its 432,667 participants, there were 5,876 cases of dementia, 2,540 cases of Alzheimer's disease, and 1,220 cases of vascular dementia that occurred over an average of 13 years of follow-up. This was compared with participants who did not have CHD, or those with CHD who had higher risks of developing dementia from any cause, Alzheimer's disease, and vascular dementia.

After adjusting the analysis for demographic and lifestyle factors, participants with coronary heart disease had a 36% increased risk of developing dementia, a 13% increased risk of developing Alzheimer's, and a 78% greater risk of developing vascular dementia. Earlier coronary heart disease-onset was associated with a 25% increased risk of dementia, a 29% increased risk of Alzheimer's disease, and a 22% increased risk of vascular dementia.

The risk of dementia rose in direct proportion to the younger age of CHD onset (per 10-year decrease in age). Participants diagnosed with CHD before age 45 had a significantly increased risk of developing dementia compared to their counterparts who did not have CHD.

**Fanfan Zheng,** Ph.D., Researcher in the School of Nursing at the Chinese Academy of Medical Sciences & Peking Union Medical College in Beijing, China, noted: "What surprised us most was the linear relationship between age of CHD onset and dementia. This shows the huge detrimental influence of premature CHD on brain health. As more people live longer and are diagnosed with CHD at a younger age, it's likely there will be a large increase in the number of people living with dementia in years to come. Healthcare professionals should be aware of individuals diagnosed with CHD at a young age. The next step is to determine whether modifying cardiovascular risk early in life will promote better brain health later in life."

According to the AHA's 2023 Statistical Update, CHD caused 382,820 deaths in 2020. The estimated rate of dementia (alone, not including Alzheimer's) in U.S. adults 65 years and older was 10.5% in 2012; with a rate of 7.3% in males, and 12.9% in females.

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# Editorial (& plantar fasciitis)

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- **Obesity:** Excess pounds put extra stress on your plantar fascia.
- **Occupations that keep you on your feet:** Factory workers, teachers and others who spend most of their work hours walking or standing on hard surfaces can be at increased risk of plantar fasciitis.

**Complications:** Ignoring plantar fasciitis can result in chronic heel pain that hinders your regular activities. You're likely to change your walk to try to avoid plantar fasciitis pain, which might lead to foot, knee, hip, or back problems.

**Diagnosis:** Plantar fasciitis is diagnosed based on your medical history and physical exam. During the exam, your healthcare professional will check for areas of tenderness in your foot. The location of your pain can help determine its cause.

**Imaging tests:** Usually, no tests are needed. Your healthcare professional might suggest an X-ray or MRI to make sure another problem, such as a stress fracture, is not causing your pain.

Sometimes an X-ray shows a piece of bone sticking out from the heel bone. This is called a bone spur. In the past, these bone spurs were often blamed for heel pain and removed surgically. But many people who have bone spurs on their heels have no heel pain.

**Treatment:** Most people who have plantar fasciitis recover in several months with conservative treatment, such as icing the painful area, stretching, and modifying or staying away from activities that cause pain.

**Medicines:** Pain relievers you can buy without a prescription such as ibuprofen (Advil®, Motrin IB®, others) and naproxen sodium (Aleve®) can ease the pain and inflammation of plantar fasciitis.

**Therapies:** Physical therapy or using special devices might relieve symptoms. Treatment may include the following.

- **Physical therapy:** A physical therapist can show you exercises to stretch the plantar fascia and Achilles' tendon and to strengthen lower leg muscles. A therapist also might teach you to apply athletic taping to support the bottom of your foot.
- **Night splints:** Your care team might recommend that you wear a splint that holds the plantar fascia and Achilles' tendon in a lengthened position overnight to promote stretching while you sleep.
- **Orthotics:** Your healthcare professional might prescribe off-the-shelf or custom-fitted arch supports, called orthotics, to distribute the pressure on your feet more evenly.
- **Walking boot, canes, or crutches:** Your healthcare provder might suggest one of these for a brief period either to keep you from moving your foot or to keep you from placing your full weight on your foot.

**Surgical or other procedures:** If more conservative measures are not working after several months, your healthcare professional might recommend the following.

- **Injections:** Injecting steroid medicine into the tender area can provide temporary pain relief. Multiple shots are not recommended because they can weaken your plantar fascia and possibly cause it to rupture. Platelet-rich plasma obtained from your own blood can be injected into the tender area to promote tissue healing. Ultrasound imaging during injections can assist in precise needle placement.
- **Extracorporeal shock wave therapy:** Sound waves are directed at the area of heel pain to stimulate healing. This is for chronic plantar fasciitis that has not responded to more-conservative treatments. Some studies show promising results, though this therapy has not been shown to be consistently effective.
- **Ultrasonic tissue repair:** This minimally invasive technology uses ultrasound imaging to guide a needlelike probe into the damaged plantar fascia tissue. The probe tip then vibrates rapidly to break up the damaged tissue, which is suctioned out.
- **Surgery:** Few people need surgery to detach the plantar fascia from the heel bone. It is generally an option only when the pain is serious and other treatments have failed. It can be done as an open procedure or through a small incision with local anesthesia.

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# Experimental Pacemaker Converts Energy From Heartbeat To Recharge Battery

On November 6, 2023, the American Heart Association (AHA) of Dallas, Texas announced proof from a principle study, that by converting mechanical energy into electrical energy, an experimental wireless, or leadless, pacemaker housing is able to partially recharge its battery.

According to the AHA, traditional (transvenous) pacemakers have tiny wires, or leads, that connect to the heart on one end and on the other end, to a generator (which includes the battery) just under the skin of the left shoulder. The leads use sensors, or electrodes, to detect the patient's heartbeat and then send electrical impulses to the heart to provide pacing, if needed.

In contrast, leadless pacemakers are all-in-one devices that are smaller than a transvenous pacemaker and reside entirely within the heart's right ventricle after being inserted through a small tube threaded up the heart via a vein in the leg. A drawback to the leadless pacemaker is that the battery cannot be easily replaced like the battery of a transvenous pacemaker. A typical battery in both traditional and wireless pacemakers lasts 6 to 15 years. In addition, removing a leadless pacemaker is difficult since it is inside the heart, so it may be necessary to implant new pacemakers alongside the previous ones that have lost their battery charge. In younger patients, who may require multiple pacemakers throughout their lives, this approach is impractical.

**Babak Nazer,** M.D., Associate Professor of Medicine at the University of Washington in Seattle (and lead study author), explained: "Mechanical and electrical energy are linked and can be exchanged back and forth. Just like ultrasound converts electrical voltage into pressure or sound, we can engineer similar materials onto implantable medical devices to convert the heart's natural oscillating pressures 'backward' into voltage to prolong battery life."

In this study, the researchers engineered three prototype devices and tested them in a cardiac pressure simulator to test their voltage output in response to oscillating pressures simulating those of the right ventricle. Similar in size to current commercially available, leadless pacemakers, the prototype devices were also about one-third the size of a AAA battery.

After placing the prototype devices into a special machine set to simulate the heart's natural pressures at a rate of 60 beats per minute, researchers recorded the energy that the device generated in response to this artificial heartbeat. They found that the best of the three prototypes harvested approximately 10% of the energy necessary to pace the "next beat," based on average pacemaker output.

Dr. Nazer added: "Our next step is to optimize materials and fabrication to improve energy harvesting efficiency, and then show we can do so consistently in long-term studies. When we can improve upon our 10% harvesting efficiency, we hope to partner with one of the major pacemaker companies to incorporate our design and housing into an existing leadless pacemaker. We hope to prolong battery life further and expand access of this product to younger patients, who would hopefully require fewer implants over their lifetime."

According to the AHA's *Heart Disease & Stroke Statistics 2023 Update*, an estimated 93,000 pacemaker and defibrillator procedures were performed for inpatients in 2018 in the United States.

**Kenneth A. Ellenbogen,** M.D., FAHA, Kimmerling Professor of Cardiology at the VCU School of Medicine in Richmond, Virginia and co-author of the 2018 ACC/AHA/HRS Guideline on the Evaluation & Management of Patients With Bradycardia & Cardiac Conduction Delay, said: "This experimental study provides valuable information on harvesting energy from the heart to recharge pacemaker batteries. These new devices could also improve patients' quality of life by requiring fewer procedures as they are smaller and last longer."

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# Current Exhibiting & Sponsoring Vendors (*to date)*
# 27th Annual NPPA Conference: August 19-22, 2024
# Horseshoe Las Vegas, Nevada *(formerly Bally's)*

## Diamond Plus Exhibitor

**Turbare Manufacturing, LLC**

## Silver Exhibitors

**Acute Care Pharmaceuticals**

**American Regent**

**Avenacy**

**AvKARE, LLC**

**Baxter**

**Dr. Reddy's Laboratories**

**Eugia US LLC**

**Hikma Pharmaceuticals USA Inc.**

**Indivior - Treatment Services**

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**Meitheal Pharmaceuticals, Inc.**

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**Pfizer, Inc.**

**Somerset Pharma, LLC**

**Viatris, Inc.**

**WG Critical Care, LLC**

**XGen Pharmaceuticals DJB**

**In addition, find approximately 51 Bronze Exhibitors *(to date)*...**
**On the "Exhibitor List" page of NPPA's website:**
www.PharmacyPurchasing.com/2024-nppa-conference-exhibitor-list

## Members-Refer An Exhibiting Vendor & Get Rewarded!

To thank our NPPA members for spreading the word about our Annual NPPA Conference to the vendors that call on them, we instituted a Sponsor Referral Award incentive program for our members, so that if you successfully refer a vendor to exhibit at our conference, you'll be rewarded for your effort.

Not only do we award more to new companies, but this incentive even applies to vendors who had previously exhibited and sponsored! (After 3+ years of not doing so.) Referral commissions range from $100 up to $600 depending on their exhibitor package/booth size as well as if they're a new or previous exhibiting company.

It's not too late to still take advantage of this Member Incentive Program! Simply ask the vendors who call on you to add your name when they submit their order, in place within our Exhibitor Prospectus & Order Form for the section to note the referral of an NPPA member.

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# Exhibiting & Sponsoring Vendors, 2024 NPPA

*Continued from Page 74*

## Sponsored Items & Programs/Events

**340B University:** 340B Prime Vendor Program Managed by Apexus

**Badge Lanyards:** XGen Pharmaceuticals DJB, Inc.

**Notepads & Pens:** Dr. Reddy's Laboratories, Inc.

**Opening Reception:** Turbare Manufacturing, LLC

**Scholarship Program:**

- ISO-MED
- Precision Dose, Inc.
- Turbare Manufacturing, LLC

**Tote Bags:** Pine Pharmaceuticals

**Cyber Cafe:** Turbare Manufacturing, LLC

**Lap Blankets:** Cipla USA, Inc.

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# Welcome, New NPPA Members!

Thanks and welcome to all listed below, for your new NPPA memberships! We encourage you to send feedback and contribute articles for this, your member-publication. Send such articles and feedback as either a Word document or within the email memo itself, to: Board@PharmacyPurchasing.com

Be sure to read the next page's "NPPA Website Resources" (which is a regular column in each *PPO* edition). This provides you with your Member-Only page's login information, which has FDA shortage alerts, recalls, and more.

Also know that we pay for published articles! See our NPPA website's "Member Incentives Program" page for the details.

### Full Pharmacy Members

**Kristi DeCarlo**, Acute Supply Coordinator, Banner Desert Medical Center, Mesa, AZ

**Candace Bear**, Pharmacy Buyer, Phoenix Children's Hospital, Phoenix, AZ

**Heather Armstrong**, Acute Supply Coordinator/Pharmacy Tech., University of AZ Cancer Center, Tucson, AZ

**Lorraine Olguin**, Pharmacy Technician & Assistant Buyer, Mercy Hospital Downtown, Bakersfield, CA

**Jose Lopez**, Pharmacy Director, San Gorgonio Memorial Hospital, Banning, CA

**Tin Diep**, Pharmacy Buyer, Mills-Peninsula Medical Center, Burlingame, CA

**Darlene Parra**, Pharmacy Buyer, Sharp Coronado Hospital, Coronado, CA

**Rhonda Anderson**, Lead Pharmacy Buyer, St. Joseph Hospital, Eureka, CA

**Robert Ruiz**, Pharmacy Buyer, Salinas Valley Health Medical Center, Salinas, CA

**Mabel Stanley**, Pharmacy Technician, Marian Regional Medical Center, Santa Maria, CA

**Genna Atalig**, Pharmacy Buyer III, Sutter Tracy Community Hospital, Tracy, CA

*Continued on Page 76*

# New NPPA Members

*Continued from Page 75*

**Melanie Welcher**, Supervisor of Pharmacy Services Line, Sutter Health (corporate office), Wilton, CA

**Erika Van Meter**, Pharmacy Technician, Aspen Valley Hospital, Aspen, CO

**Katie Place**, Business Manager, Nemours Children's Hospital, Wilmington, DE

**Courtney Hopkins**, Pharmacy Technician, North Canyon Medical Center, Gooding, ID

**Alison Tyner**, Pharmacy Inventory Specialist, SIH Cancer Institute, Carbondale, IL

**Kathryn Johnson**, Pharmacy Inventory Specialist II, SIH St. Joseph Memorial Hospital, Murphysboro, IL

**Chauncey Williamson**, Pharmacy Buyer, Karmanos Cancer Institute, Detroit, MI

**Carrie Blonde**, Pharmacy Buyer, Oaklawn Hospital, Marshall, MI

**Jason Hexom**, Pharmacy Distribution, State of Minnesota (MMCAP), St Paul, MN

**Whitney Occhuzzo**, Pharmacy Buyer, Western Missouri Medical Center, Warrensburg, MO

**Josie Quick**, Senior Pharmacy Technician & Inventory Specialist, Sanford Health South University Medical Center, Fargo, ND

**Stephanie Norris**, Specialty Pharmacy Technician & Prior Authorization Specialist, Western New York Bloodcare Medical Center, Buffalo, NY

**Eunice Manalili-Torina**, Pharmacy Tech-Buyer, Nassau University Medical Center, East Meadow, NY

**Amy Ho**, Pharmacist, NYC Health & Hospitals-Metropolitan, New York, NY

**Shawna (Morey) Mulligan**, Pharmacy Buyer, Blythedale Children's Hospital, Valhalla, NY

**Chad Doan**, Pharmacy Buyer, Ohio State University Wexner Medical Center, Chillicothe, OH

**Sharon Bingham**, Pharmacy Buyer, The Christ Hospital, Cincinnati, OH

**Erin Ridhibhinyo**, Pharmacy Inventory Coordinator, Nationwide Children's Hospital, Columbus, OH

**Kelly Frost**, 340B Compliance Auditor/Pharmacy Buyer, TriHealth corporate office, Lebanon, OH

**Patrik Jones**, Pharmacist, Oklahoma City Indian Clinic Pharmacy, Oklahoma City, OK

**Miah Hayward**, Pharmacy Purchaser, Oklahoma City Indian Clinic Pharmacy, Oklahoma City, OK

**Deborah Faucette**, Billing/Contracting & Pharmacist Manager, Oklahoma City Indian Clinic Pharmacy, Oklahoma City, OK

**Charles Simon**, Pharmacy Contract Manager, Sutter Health (corporate office), Sacramento, CA

**Cassandra Fotta**, Pharmacy Purchasing Associate, St. Luke's Allentown Campus, Allentown, PA

**Dana Picciotti**, Materials Manager, Pentec Health-503B Pharmacy, Boothwyn, PA

**Ellen Pappas**, Pharmacy Purchasing Associate, Geisinger St Luke's Hospital, Orwigsburg, PA

**Amanda Henstein**, Pharmacy Operations Coordinator, Monument Health Rapid City Hospital, Rapid City, SD

**Carla Carroll**, Pharmacy Buyer, CHI St. Joseph Health Regional Hospital, Bryan, TX

**Esther Holsworth**, Pharmacy Buyer, UTSW William P. Clements University Hospital, Dallas, TX

**Jeff Stitt**, Pharmacy Tech III, Baylor, Scott & White All Saints Med. Ctr., Fort Worth, TX

**Roxanne Roebuck**, Pharmacy Buyer, Hunt Regional Medical Center, Greenville, TX

**Kristian Pickerill**, Pharmacy Purchaser, Methodist Midlothian Medical Center, Midlothian, TX

**Andres Flores**, Pharmacy Purchasing Manager, Methodist Hospital, San Antonio, TX

**Marissa Rhoades**, Pharmacy Inventory Supervisor, MChest Pharmacy (corporate office), Tyler, TX

**Amanda Eley**, Pharmacy Technician Supervisor, Richmond VA Medical Center, Richmond, VA

# Thanks To Renewing NPPA Members

**Full Pharmacy Members**

**Allen Sutherland**, Regional Pharmacy Buyer, St. Joseph's Hospital & Medical Center, Phoenix, AZ

**Ashley Harris**, Pharmacy Buyer, Summit Healthcare Regional Medical Center, Show Low, AZ

**LaDonna Triplett**, Lead Pharmacy Technician, Adventist Health Mendocino Coast Hospital, Fort Bragg, CA

**Eugene Gagaring**, Pharmacy Buyer, UCSD Medical Center, La Jolla, CA

**Erin Miller**, Lead Pharmacy Buyer, Sonora Community Hospital-Adventist Health, Sonora, CA

**Theresa Sedillos**, Pharmacy Operations Manager/Purchasing Agent, Rose Medical Center, Denver, CO

**Angela Westdorp**, Pharmacy Tech Distribution Specialist, Sarasota Memorial Hospital-Venice, North Venice, FL

**Regina Smith,** Pharmacy Buyer & Inventory Specialist, WellStar Health Consolidated Service Centers Pharmacy, Lithia Springs, GA

**Elizabeth Posada**, 340B Program Coordinator/Pharmacy Buyer, Robert Wood Johnson University Hospital, New Brunswick, NJ

**Marquitta Scott**, Pharmacy Buyer, Roper St. Francis Hospital, Charleston, SC

**Rodney Elliott**, Pharmacy Purchasing Agent, CHI Memorial Hospital, Chattanooga, TN

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**Executive (GPO) Members**

**Paula Gurz**, Sr. Director of Pharmacy Contracting, Premier, Inc., Lake Wylie, SC

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**Corporate (Vendor) Members**

**Dana Ryan**, Key Account Manager, Kesin Pharma Corporation, San Diego, CA

**Elizabeth Faust**, 340B Compliance & Education Specialist, Apexus, LLC, Raleigh, NC

**Joel Rosenstack**, Chief Commercial Officer of North America Injectables, Hikma Pharmaceuticals USA, Inc., Berkeley Heights, NJ

**Bob Braverman**, President, Medi-Dose, Inc./ EPS, Inc., Ivyland, PA

**Amy Lope**, Senior Marketing Communications Manager, Sagent Pharmaceuticals, Inc., Mars, PA

**Mark Mendenhall**, VP of Institutional Sales, Somerset Pharma, LLC, Franklin, TN

**Chris Davies**, Director of Business Development, Winfield Laboratories, Inc., Sandy, UT

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# New NPPA Members

*Continued from Page 76*

**Karen Bhangav**, Pharmacy Buyer, PeaceHealth St. Joseph Medical Center, Blaine, WA

**Sara Marquardt**, Pharmacy Purchasing Associate, ThedaCare Regional Medical Center, Appleton, WI

**Savannah Herman**, Pharmacy Buyer/Technician, Black River Memorial Hospital, Black River Falls, WI

**Heather Heidrich**, Pharmacy Buyer, Banner Wyoming Medical Center, Casper, WY

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**Corporate (Vendor) Members**

**Karyn Bundrant**, Vice President of Marketing, Avenacy, Schaumburg, IL

**Ashish Manjrekar**, Director of Marketing & Portfolio, Zydus Pharmaceuticals USA Inc., Pennington, NJ

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# NPPA Member Resources Online

NPPA Members: here below please find all of the information about the resources you can utilize on the NPPA website, www.PharmacyPurchasing.com

**"Member Only Resources" page of the NPPA website:** To access this page, the password is: ***"npparesources"*** (all 1 word, case-sensitive). Also, know this page's login is one of the benefits of your paid membership, so please do not share this information with those who are not current NPPA members. On this page, you will find the following sections and information.

**"Breaking News, Recalls & Alerts" section:** for any important alerts and recalls that we feel are relevant for our members to know about as soon as possible. To alert you of new posts there before having to login, first check our site's Home page under "What's New," where you'll find "Breaking Recalls & Other News," with a date next to it, to show the last time something important was added there you may want to read more about.

**"Shortages & Discontinuations" section,** which includes:

a) A link to sign up to receive the FDA's "Daily Drug Shortages Bulletin." This way, you can keep up with shortages as soon as possible, and be able to quickly share that information with the rest of your staff when applicable, so they're also aware of what medications are currently short.

b) A live feed from the FDA website, with current product recalls and alerts from their MedWatch Safety Report.

c) A live feed from the American Society of Health System Pharmacists (ASHP) website, that lists the latest reported "Current" & "Resolved" Drug Shortages.

d) A live feed from the ASHP website, that lists the latest reported "Discontinued Drugs."

**"Other Industry Resources & Links":** which includes links to the following: Various websites for additional drug shortage references; Latest flu & vaccine information from the CDC; Information on Emergency & Pandemic Preparedness; Recycling information for healthcare facilities; Educational information; Networking Tools, such as for inexpensive business cards to bring to the NPPA Conference; Career Opportunity websites for your profession.

**Facebook *"Pharmacy Buyers"* group:** one of our NPPA members and Annual Conference attendees **Cassidy Russell,** took it upon herself to setup a Facebook *"Pharmacy Buyers"* group page at the end of 2019, which has been very popular from the start and continues to grow. Buyers there post various questions to each other or provide general information and support. To join the group, search on "Pharmacy Buyers" in your Facebook account, or visit: www.facebook.com/groups/334035183936954

*NPPA hopes these resources help you to be an even better Pharmacy Buyer!*

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# E-Blast & NPPA Website Banner Advertising - 2024

**Vendor E-Blasts & RxBuyer E-News Advertising**

***RxBuyer eNews*:** distributed 4 times a year to approximately 1,800, as an advertorial type section with photos, company logos, text, and hyperlinks allowed (within NPPA's existing eNews).

**Vendor E-Blasts:** your company's devoted content taking over the whole E-Blast, with photos, company logos, text, and hyperlinks.

**Additional Details & Submitting Order Requests:** see information and respective Order Forms, on the Advertising page of the NPPA website, at: www.pharmacypurchasing.com/eblast-advertising

**Website Banner Advertising**

**Banner Ads on the NPPA website with hyperlinks** (various sizes & page placements available).

**For Rates, Discounts, Sizes/Placement Availability & Order Forms:** see our website's Advertising page, at: www.pharmacypurchasing.com/website-banner-ads

**For Questions or to send Order Forms for the above Advertising options,**
Send email to: Advertising@PharmacyPurchasing.com

# Advertising In PPO (Regular & Digital Version) - 2024

**NPPA's member-publication, *Pharmacy Purchasing Outlook (PPO)***

Black & White Ads only, unless doing Color Inserts or in our Digital *PPO* E-Version (see options below)

| **Premium Positions (full page, right facing)** | **Gross Rate** |
|---|---|
| Outside Back Cover | $675.00 |
| Inside Front Cover | $650.00 |
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| Center Spread (2 pages) | $600.00 (x 2) |
| Editorial-Adjacent | $575.00 |

Note: Premium Ad Positions are reserved & paid in advance, please inquire first.

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|---|---|
| All Other Inside Pages | $550.00 |

| **Color Insert Positions** | **Gross Rate** | **Color Front Cover Ads** | **Gross Rate** |
|---|---|---|---|
| Color Insert (loose in envelope) | $1.100.00 | Cover Sheet, 1/2 Page | $1,750.00 |
| Color Insert (glued in *PPO*) | $1,450.00 | Cover Sheet, Full Page | $2,200.00 |

**Discounts Available & Submitting Order Requests:** see details in the *PPO* Ad Rates & Specs Sheet Order Form, found on the Advertising page of the NPPA website, at: www.pharmacypurchasing.com/ppo-advertising

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**NPPA's Digital E-Version of *Pharmacy Purchasing Outlook (PPO)***

**Premium Position Options & Gross Rate**

Editorial Adjacent-Color (+URL): **$750**
Editorial Adjacent-B&W (+URL): **$450**
Inside Front Cover-Color (+URL): **$725**
Inside Front Cover-B&W (+URL): **$425**
Inside Back Cover-Color (+URL): **$675**
Inside Back Cover-B&W (+URL): **$375**
Outside Back Cover-Color (+URL): **$675**
Outside Back Cover-B&W (+URL): **$375**
Center Spread-Color (+URL): **$1,250** (2 pages @ $625 ea.)
Center Spread-B&W (+URL): **$650** (2 pages @ $325 ea.)

**Standard Inside Ad Positions, Gross Rate** ***(right facing, unless a spread)***

Standard Inside Positions (Color+URL): **$625**
Standard Inside Positions (B&W+URL): **$325**

**URL Links:** hyperlinks to your web address of choice will be provided on each Ad Page itself; as well as a "jump to page" link in our Table of Contents on Page 3 of each Digital *PPO* edition where your company's Ad Pages are listed (to go directly to your Ad Pages within the publication, via a link on the page numbers).

**Discounts Available & Submitting Order Requests:** see details in the *PPO* Ad Rates & Specs Sheet Order Form, found on the Advertising page of the NPPA website, at: www.pharmacypurchasing.com/advertising-digital-ppo

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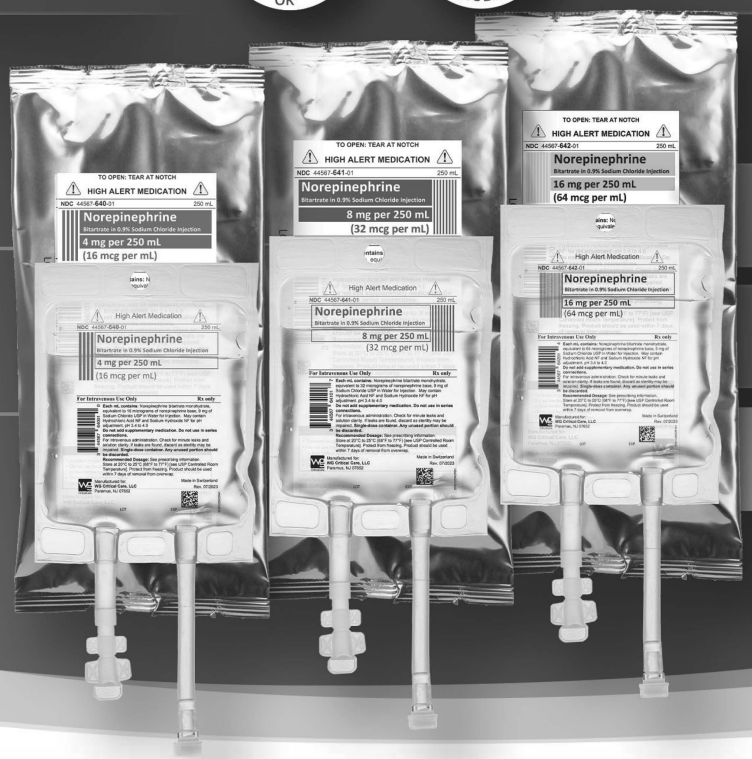


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