Pharmacy Purchasing Outlook

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

Volume XXVIII Issue 4, June 2021 Published by NPPA/Summerdale Enterprises, Inc.

Magnets In Certain Cell Phones & Smart Watches Can Interfere With Some Implanted Cardiac Devices

On June 2, 2021, the American Heart Association (AHA), Dallas, Texas announced that people who have a pacemaker or an implantable cardioverter defibrillator should be aware that the magnets used in the wireless charging technology for the series 12 models of the Apple iPhone, can affect how such cardiac devices work, if the phones are stored or used in close proximity to the implanted cardiac device.

In a small study, researchers found when the phone was held directly over the skin near the implantable cardiac devices or directly over the still-packaged cardiac device, the magnetic technology in the iPhone 12 Pro Max® caused interference in nearly 80% (11 of 14) of the pacemakers and implantable cardioverter defibrillators evaluated.

Preceding this announcement by the AHA, on May 13, the FDA also issued a similar alert regarding magnet technology in portable electronics such as cell phones and smart watches that have magnets, to say that they recommend keeping all electronic devices with magnets at least 6 inches away from implanted medical devices, such as pacemakers and defibrillators. Apple offers the same guidance regarding its MagSafe products.

Michael Wu, M.D., Assistant Professor of Medicine, Clinician Educator, and Director of the Clinical Cardiac Electrophysiology Fellowship Program at the Rhode Island and Miriam Hospital's Lifespan Cardiovascular Institute and Brown University's Warren Alpert School of Medicine (and lead investigator of the drug's study trial), said: "We have always known that magnets can interfere with cardiac implantable electronic devices, however, we were surprised by the strength of the magnets used in the iPhone 12 magnet technology. In general, a magnet can change a pacemaker's timing or deactivate

Continued on Page 13

FDA Updates List Of Off-Patent, Off-Exclusivity Drugs Without Generic

On June 22, 2021, the FDA announced they have published an update to the List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic ("OPOE list"), which includes approved New Drug Applications (NDA's) for drug products that are not protected by patents or exclusivities at the time of the update, and for which the FDA has not approved an Abbreviated New Drug Application (ANDA) referencing that NDA product.

The updated OPOE list is available in both PDF and Excel formats, but the PDF version will have the full details and methodology for each medication.

To view and save the new OPOE list, visit the following FDA web page: www.fda.gov/drugs/abbreviated-new-drug-application-anda/list-patent-exclusivity-drugs-without-approved-generic

Highlights Inside This Edition

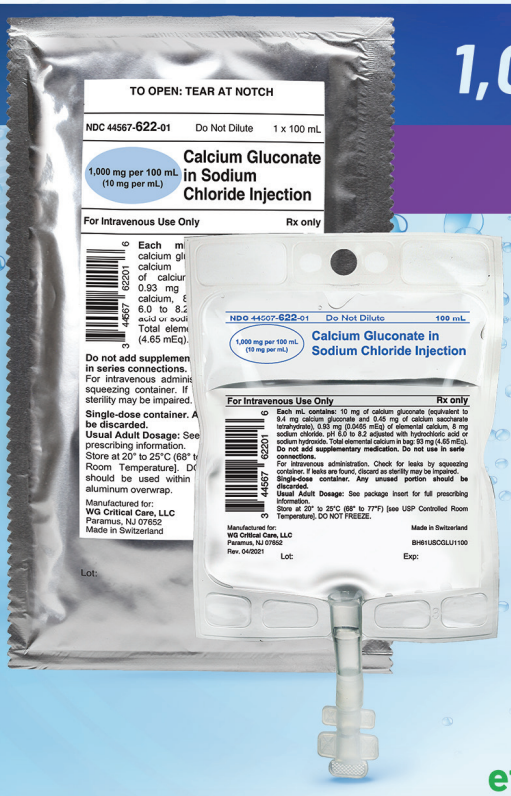
The FDA maintains the OPOE list to improve transparency and encourage the development and submission of applications under an abbreviated approval pathway for drugs with limited competition. The agency updates the list every 6 months (in June and December) to ensure continued transparency regarding drug products where increased competition has the potential to provide significan't benefit to patients. This list is also useful within the FDA, as they develop additional product-specific guidances and other resources to assist prospective ANDA applicants and encourage the development and submission of ANDA's in markets with little competition.

For more information on the FDA's efforts to bring more drug competition to the market and address the high cost of medicines, visit the Drug Competition

Continued on Page 67

Now Available! Another Choice

Calcium Gluconate
in Sodium Chloride Injection



1,000 mg per 100 mL (10 mg per mL)

FDA APPROVED READY TO USE BAG

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NDC # 44567	Bar Code	Total Amount	Fill Volume	Container Type	Concentration	Pack Size	Shelf Life	WHOLESALER ITEM NUMBERS			
								Amerisource Bergen	Cardinal	McKesson	Morris & Dickson
622 - 24		1,000 mg	100 mL	100 mL Premix Bag	10 mg/mL	24	24 months	10260989	5740469	2349777	106666
620 - 24		1,000 mg	50 mL	100 mL Premix Bag	20 mg/mL	24	36 months	10209105	5503305	3672185	511089
621 - 24		2,000 mg	100 mL	100 mL Premix Bag	20 mg/mL	24	36 months	10225251	5547013	3959640	718312

Indications and Usage

Calcium Gluconate in Sodium Chloride Injection is a form of calcium indicated for pediatric and adult patients for the treatment of acute symptomatic hypocalcemia.
Limitations of Use: The safety of Calcium Gluconate in Sodium Chloride Injection for long term use has not been established.

Important Safety Information

Contraindicated in hypercalcemia and in neonates receiving ceftriaxone. Warnings and Precautions: cardiac arrhythmias may occur with concomitant cardiac glycoside use; use caution when administering with ceftriaxone as a precipitate may form in the IV line; tissue necrosis and calcinosis may occur with or without extravasation; hypotension, bradycardia and cardiac arrhythmias may occur with rapid administration; contains aluminum which may cause toxicity. The most common adverse events are local soft tissue inflammation and necrosis; calcinosis cutis and calcification related to extravasation; vasodilation, decreased blood pressure, bradycardia, cardiac arrhythmia, syncope and cardiac arrest.

Please see full Presribing Information, inluding Warnings, Precautions, and Important Safety Information for this product at the WGCC website.

References: 1. On file WG Critical Care, LLC. To request data on file, please contact Customer Service at 1-888-493-0861 or CustomerService@wgccrx.com

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Join Us For The 25th Annual NPPA Conference This August, 2022!

Be sure to plan ahead and mark your calendars for the ***next*** NPPA Conference, at Bally's Las Vegas over August 9-11, 2022.

2022 NPPA: Tuesday August 9 through Thursday August 11

Pre-Conference 340B University: Monday August 8

Registration for Attendees is expected to ***open in late February 2022.*** Look for updates by email and on our NPPA website's Home Page on the right, under "NPPA Conference News."

In addition, an optional **340B University event will *likely* be offered** by the 340B Prime Vendor Program Managed By Apexus, on Monday, August 8th, the day before our NPPA Conference begins. Registration with Apexus usually opens in April (check our website for updates around that time, as well as our email announcements).

Bally's hotel room rates for our 2022 NPPA Group Room Block are currently ***under negotiation,*** so we'll report back on that once determined.

Pharmacy Purchasing Outlook (ISSN: 1094-9747)
Member-publication of NPPA (National Pharmacy Purchasing Association)
Issued 10 times per calendar year (monthly except February and August)
Published by: Summerdale Enterprises, Inc., dba NPPA

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NPPA Membership Rates: $90, 1-year; $170, 2-years (comes with 7 editions/year of *Pharmacy Purchasing Outlook*, the member-publication of NPPA). Issues are distributed via First Class U.S. Mail, by the end of the first week of the month after the publication issue month. See details on our website.

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Within This Edition

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Editorial

By Pamela Herold
NPPA Editorial & Event Assistant

Medication Disposal

There are a lot of things in this world that are aggravating and knowing what to do with expired home medications was at the top of my list when I worked in the hospitals. But disposing of medications that are outdated or discontinued no longer has to be a hair pulling experience and is a thing of the past.

Someone passes away or a doctor discontinues a patient's medication, and most times that bottle will remain in the cupboard. In time, it gets pushed to the back until it is discovered years later, and somebody tries to figure out what to do with it.

After my mother-in-law passed away over 20 years ago, our family found about 5 paper grocery bags filled with all sorts of drugs: hydromorphone, morphine, loads of other pain medications, insulin and syringes, inhalers of different types, a couple of anti-depressant meds, and lots of non-prescription products. Once the shock wore off, we all looked at each other and asked: *"What the heck do we do with all this stuff?"*

One of us started calling pharmacies asking if they could dispose of the medications, next it was calling the local hospital, nursing homes, the trash company, finally the police department. Not one person we spoke with back then knew where to take these controlled substances and over-the-counter (OTC) pharmaceuticals for destruction. How frustrating! First, we contemplated flushing everything down the toilet. Then we decided to fill a bucket with dirt and proceeded to dump in the pills, capsules, empty all the liquid bottles, and open every medicine package, and mixed it together in the bucket. After it was all nicely blended, we poured it into a couple of trash bags and into the trash dumpster it went.

That was then. However, today we have solutions to resolve this frustrating issue! Even just a few years back there did not seem to be information about where, we as the public, can go to drop off our unused medications for disposal. The Drug Enforcement Administration (DEA) has a great resource for locating places for pharmaceutical disposal online (www.deadiversion.usdoj.gov/drug_disposal/takeback). From there, look for the link to "Search for Year-Round Pharmaceutical Disposal Locations." Over the years, the DEA has expanded and improved this information and there are literally thousands of locations for our patients and their families to drop off unused drugs by searching by zip code or city. This link also contains details about their National Prescription Take Back Day held every year in April and October. Results of the amount of prescription medications dropped off are posted shortly after each event on their website.

The April 2021 National Prescription Drug Take Back Day proved to be very successful, with collecting 829,543 pounds of unwanted, expired, and unused medications across the country. Just the Houston, Texas DEA Field Division alone, collected 27,850 pounds! Since inception of this Take Back program in 2010, the public has turned in over 985,392 pounds of medication. That's over 493 tons!

It's incredible the tremendous amount of prescription drugs turned in and removed from homes every year, thus preventing addiction and potential overdose.

Recently, I cleaned out my medicine cabinet and found 4 bottles of expired medications, 2 of which were prescriptions. It's difficult to imagine the vast amount of expired or unused drugs in medicine cabinets across the United States that need to be destroyed. With over 11,000 year-round authorized collection sites nationwide, we have a wide selection of places to drop off those medications, both prescription and OTC.

The DEA Take Back webpage is a great resource for different types of disposal ideas and locations that meet different needs (www.dea.gov/press-releases/2021/05/03/dea-and-partners-announce-results-20th-national-prescription-drug-take). There is a link leading to "Home Disposal Methods," which explains the "Do's & Don'ts" associated with this option.

The days of flushing any and all medications down the drain are long gone, since it's very harmful to our environment. Note the Take Back website is also very helpful for instructing proper disposal for OTC meds.

Continued on Page 68

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

Aminocaproic Acid Tablets - Edenbridge Pharmaceuticals

On June 14, 2021, Edenbridge Pharmaceuticals, LLC of Parsippany, New Jersey announced they received final FDA approval for their Abbreviated New Drug Application (ANDA) for Aminocaproic Acid Tablets 500mg.

This product compares to Amicar® Tablets by Akorn, Inc. It is indicated to treat bleeding episodes in people with certain medical conditions such as aplastic anemia (lack of blood cells and platelets), cirrhosis of the liver, placenta abruptio (early separation of the placenta in pregnancy), urinary bleeding, and certain types of cancer.

Arformoterol Tartrate Inhalation Solution - Cipla & Glenmark

On June 23, 2021, the following two (2) companies announced they received final FDA approval for Arformoterol Tartrate Inhalation Solution 15mcg/2mL, as detailed below.

- Cipla USA Inc. of Miami, Florida.
- Glenmark Pharmaceuticals Inc., USA of Mahwah, New Jersey *(available now in unit-dose vials)*.

This product is AN-rated to Brovana® Inhalation Solution by Sunovion Pharmaceuticals Inc., which had recent annual U.S. sales (ending April 2021) of $438 million, according to IQVIA®. It is a long-acting beta-2 adrenergic agonist (beta-2 agonist) indicated for the long-term, twice daily (morning & evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Carfilzomib For Injection - Breckenridge Pharmaceutical/Natco Pharma

On June 15, 2021, Breckenridge Pharmaceutical, Inc. of Berlin, Connecticut and Natco Pharma Ltd. of Hyderabad, India jointly announced they received final FDA approval of its Abbreviated New Drug Application (ANDA) for Carfilzomib Powder for Injection, for intravenous (IV) use, in the strengths of 10mg and 60mg.

This product compares to Kyprolis® for Injection by Onyx Therapeutics, Inc. (an Amgen subsidiary), which had recent annual U.S. sales (ending April 2021) of $711 million, according to IQVIA. It is indicated to treat multiple myeloma; and is sometimes given with other medicines when treating relapsed multiple myeloma.

Onyx Therapeutics, Breckenridge, and Natco have reached a Settlement Agreement and the District Court case against Breckenridge and Natco has been dismissed. By virtue of the settlement, Breckenridge has been granted a license permitting the launch of its generic carfilzomib product on a date that is held as confidential in 2027 or sooner depending on certain occurrences. The parties cannot make further comment as to the terms of the Settlement Agreement.

Desipramine HCl Tablets - Alembic Pharmaceuticals

On July 8, 2021, Alembic Pharmaceuticals, Inc. of Bridgewater, New Jersey announced they received final FDA approval for their Abbreviated New Drug Application (ANDA) for Desipramine HCl Tablets in the strengths of: 10mg, 25mg, 50mg, 75mg, 100mg, and 150mg.

This product compares to Norpramin® Tablets by Validus Pharmaceuticals LLC. It is indicated for the treatment of depression.

Recent annual U.S. sales (ending March 2021) of the generic product in these same strengths were approximately $7 million, according to IQVIA.

Doxycycline For Injection - Hikma Pharmaceuticals

On June 25, 2021, Hikma Pharmaceuticals USA Inc. of Eatontown, New Jersey announced their ***launch*** of Doxycycline for Injection 100mg.

Continued on Page 8

INJECTABLES

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Generic Approvals & News

Continued from Page 6

This product is an antibiotic indicated to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. It is used to treat various bacterial infections, including pneumonia and other respiratory tract infections.

Recent annual U.S. sales of the generic product in this strength were $43 million, according to IQVIA.

Emtricitabine/Tenofovir Disoproxil Fumarate Tablets Launch - Apotex

On June 17, 2021, Apotex Corp. of Weston, Florida announced their ***launch*** of Emtricitabine/Tenofovir Disoproxil Fumarate Tablets 200mg/300mg, available in 30-count bottles (NDC #60505-4202-03).

This product compares to Truvada® Tablets by Gilead Sciences, Inc. It is indicated for the following:

- In combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 17kg;
- In both at-risk adults and adolescents weighing at least 35kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection.

Ganciclovir For Injection Launch - Hikma Pharmaceuticals

On June 22, 2021, Hikma Pharmaceuticals USA Inc. of Berkeley Heights, New Jersey announced their ***launch*** of Ganciclovir for Injection 500mg.

This product is indicated for the treatment of cytomegalovirus (CMV) retinitis in immunocompromised adult patients, including patients with Acquired Immunodeficiency Syndrome (AIDS), and for the prevention of CMV disease in adult transplant recipients at risk for CMV disease.

Recent annual U.S. sales (ending April 2021) were approximately $8 million, according to IQVIA.

HydrALAZINE HCl Injection Launch - American Regent

On July 1, 2021, American Regent, Inc. of Melville, New York announced their ***launch*** of HydrALAZINE HCl Injection 20mg/mL, supplied as 1mL Single Dose Vial in a 25-count shelf pack (NDC #0517-0901-25).

This product compares to Apresoline® Injection by Novartis *(now discontinued)*. It is indicated for severe essential hypertension when the drug cannot be given orally or when there is an urgent need to lower blood pressure.

Joann Gioia, Associate VP of Commercial Operations & National Accounts at American Regent, stated: "An important part of our company's mission is to assist in mitigating shortages and ensuring supply of critical medications whenever possible. To that end, we are pleased to add HydrALAZINE HCl Injection to our robust line of products that are formulated, filled and finished at our U.S.-based manufacturing facilities."

Icosapent Ethyl Capsules Launch - Dr. Reddy's Laboratories

On June 22, 2021, Dr. Reddy's Laboratories, Inc. of Princeton, New Jersey announced their ***launch*** of Icosapent Ethyl Capsules 1Gm, available in 120-count bottles.

This product compares to Vascepa® Capsules by Amarin Pharma, Inc. It is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe hypertriglyceridemia.

Note: this product is ***not*** approved for the following indication: as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels and established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease.

Isotretinoin Capsules Launch - Upsher-Smith Laboratories

On June 25, 2021, Upsher-Smith Laboratories, LLC of Maple Grove, Minnesota announced their ***launch*** of Isotretinoin Capsules 40mg, available in 30-count boxes (NDC #0245-0575-01).

This product is AB2-rated to Absorica® Capsules by Sun Pharmaceutical Industries, Inc. It is a retinoid indicated for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5mm or greater.

Recent annual U.S. sales (ending April 2021) of the generic and brand product were $156 million, according to IQVIA.

Note: because of significant adverse reactions associated with its use, it is reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.

Ivermectin Cream 1% Launch - Teva

On June 16, 2021, Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey announced their ***launch*** of Ivermectin Cream 1%, available in 45Gm/Tube (NDC #00591-4052-89).

Generic Approvals & News

Continued from Page 8

This product compares to Soolantra® Cream by Galderma Laboratories, L.P., which had recent annual U.S. sales (ending April 2021) of more than $115 million, according to IQVIA. It is a topical cream, indicated for the treatment of inflammatory lesions of rosacea.

Nitrofurantoin Capsules - Alembic Pharmaceuticals

On July 1, 2021, Alembic Pharmaceuticals, Inc. of Bridgewater, New Jersey announced they have received final FDA approval for its Abbreviated New Drug Application (ANDA) for Nitrofurantoin Capsules (Macrocrystals) in the strengths of: 25mg, 50mg, and 100mg.

This product compares to Macrodantin® Capsules by Alvogen Malta Operations Ltd., which had recent annual U.S. sales (ending March 2021) of $23 million, according to IQVIA. It is indicated for the treatment of urinary tract infections when due to susceptible strains of *Escherichia coli*, *enterococci*, *Staphylococcus aureus*, and certain susceptible strains of *Klebsiella* and *Enterobacter* species.

Rufinamide Tablets Launch - Hikma Pharmaceuticals

On June 24, 2021, Hikma Pharmaceuticals USA Inc. of Eatontown, New Jersey announced their ***launch*** of Rufinamide Tablets in the strengths of 200mg and 400mg.

This product compares to Banzel® Tablets by Novartis Pharmaceuticals Corporation. It is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in adults and pediatric patients ages 1 year and older.

Recent annual U.S. sales (ending April 2021) of the generic product in these strengths were $285 million, according to IQVIA.

Brian Hoffmann, President of Hikma Generics, commented: "We are proud to be among the first wave of generics to provide this important medicine. Hikma also markets Rufinamide Oral Suspension and we are pleased to add this new formulation to our portfolio. This launch demonstrates our ability to successfully deliver on our pipeline and launch new products, improving patients' access to high-quality generic medicines."

Testosterone Topical Solution (C-III) - Alembic Pharmaceuticals/Aleor Dermaceuticals

On June 16, 2021, Alembic Pharmaceuticals Inc. of Bridgewater, New Jersey (and parent company in India) and its joint venture company Aleor Dermaceuticals Ltd. of Gujurat, India announced they received final FDA approval for an Abbreviated New Drug Application (ANDA) for Testosterone Topical Solution 30mg per pump actuation.

This product compares to Axiron® Topical Solution by Eli Lilly & Company.

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

Recent annual U.S. sales (ending March 2021) of the generic product in this strength were $21 million, according to IQVIA.

Triamcinolone Hexacetonide Launch - Medexus Pharmaceuticals

On June 9, 2021, Medexus Pharmaceuticals Inc. of Chicago, Illinois announced the ***launch*** of Triamcinolone Hexacetonide Injectable Suspension 20mg/mL in the United States via the FDA's Center for Drug Evaluation & Research (CDER) Drug Shortage program.

Triamcinolone Hexacetonide (TH) is indicated for intra-articular, intrasynovial, or periarticular use in adults and adolescents for the symptomatic treatment of subacute and chronic inflammatory joint diseases, including: rheumatoid arthritis, juvenile idiopathic arthritis (JIA), osteoarthritis and

Continued on Page 10

Generic Approvals

Continued from Page 9

post-traumatic arthritis, synovitis, tendinitis, bursitis, and epicondylitis.

To address the ongoing shortage of TH in the United States, Medexus is coordinating with Ethypharm SAS of Saint-Cloud, France, its licensing partner, to generate the data needed to support an Abbreviated New Drug Application (ANDA) filing in an expedited timeframe.

First Generic Products

Formoterol Fumarate Inhalation Solution (Generic Perforomist®) Launch - Teva

On June 22, 2021, Teva Pharmaceuticals USA, Inc., of Parsippany, New Jersey announced their ***launch*** of Formoterol Fumarate Inhalation Solution for nebulization 20mcg/2mL, available as individually barcoded unit-dose vials, in packages of both 30-count (NDC #00093-4061-30) and 60-count (NDC #00093-4061-06).

This product is indicated to treat bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis as well as emphysema.

Note that this product is ***only*** for use ***with*** a nebulizer. It is meant for long-term use, to be taken twice daily, to improve the symptoms of COPD for better breathing.

Formoterol Fumarate is a long-acting beta2 adrenergic agonist (LABA) used to control the symptoms of COPD in adults. LABA medicines help the muscles around the airways in the lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath.

This is the ***first generic*** of Perforomist® Inhalation Solution by Viatris Inc., which had recent annual U.S. sales (ending March 2021) of $299 million, according to IQVIA.

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Discontinued Drugs

Albuterol Sulfate Aerosol By Endo Pharmaceuticals

On July 6, 2021, the FDA announced that Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania (with labeling by Par Pharmaceutical) has discontinued the manufacture of Albuterol Sulfate Aerosol Metered Dose Inhaler 90mcg, with 200 doses per actuator (NDC #0254-1007-52).

This product is a bronchodilator indicated to treat or prevent bronchospasm or narrowing of the airways in the lungs in people with asthma or certain types of chronic obstructive pulmonary disease (COPD); or to prevent exercise-induced bronchospasm.

Aptivus® Oral Solution

On June 29, 2021, the FDA announced that Boehringer Ingelheim Pharmaceuticals, Inc. of Ridgefield, Connecticut will discontinue the manufacture of Aptivus® (tipranavir) Oral Solution 100mg/mL, in 90mL glass bottles (NDC #0597-0002-01).

This product is an antiviral medicine, and when used together with ritonavir, is indicated to treat human immunodeficiency virus (HIV) infection, the virus that can cause AIDS (acquired immunodeficiency syndrome).

Clindamycin Phosphate Topical Solution 1% By Teligent

On June 21, 2021, the FDA announced that Teligent Pharma, Inc. of Buena, New Jersey will be discontinuing Clindamycin Phosphate Topical Solution 1% in bottles, as detailed below.

- **30mL:** NDC #52565-018-29.
- **60mL:** NDC #52565-018-59.

This product is an antibiotic indicated to treat severe acne in adults and children who are at least 12 years old.

Clobetasol Propionate Ointment 0.05% By Teligent

On June 21, 2021, the FDA announced that Teligent Pharma, Inc. of Buena, New Jersey will discontinue the manufacture of Clobetasol Propionate Ointment 0.05%, in bottles as detailed below.

- **15Gm:** NDC #52565-039-15.
- **30Gm:** NDC #52565-039-30.
- **45Gm:** NDC #52565-039-45.
- **60Gm:** NDC #52565-039-60.

This product is a corticosteroid indicated to treat inflammation and itching caused by plaque psoriasis and skin conditions that respond to corticosteroid medication.

Cytotec® Tablets

On June 14, 2021, the FDA announced that Pfizer Inc. of New York City has discontinued the manufacture of Cytotec® (misoprostol) Tablets 100mcg, in 120-count bottles (NDC #0025-1451-20).

This product is indicated to prevent stomach ulcers when taking aspirin or other non-steroidal anti-inflammatory drugs (NSAID's).

Continued on Page 12

American Health Packaging®

New products

Reference guide | May 2021

Hospital unit dose

AB 8-digit #	Cardinal Health #	McKesson #	Morris & Dickson #	Product description	Strength	UD size	NDC 11
10251783	5686407	1581669	930750	Atomoxetine Capsule	25 mg	30 UD	60687-0567-21
10254220	3703665	2302917	981878	Budesonide Capsule	3 mg	20 UD	60687-0596-32
10124030	4907010	2027480	612515	Calcium Acetate Capsule	667 mg	100UD	68084-0479-01
10251391	5682570	1578202	919258	Diltiazem HCl Tablet	30 mg	100 UD	60687-0562-01
10251956	5687223	1583525	921866	Diltiazem HCl Tablet	60 mg	100 UD	60687-0573-01
10251974	5687330	1584333	921882	Diphenoxylate HCl/Atropine Sulfate Tablet (C-V)	2.5 mg/0.025 mg	100 UD	60687-0569-01
10254113	5703590	3790623	981910	Famotidine Tablet	20 mg	100 UD	60687-0595-01
10254284	5704150	3901725	982025	Fluphenazine HCl Tablet	5 mg	100 UD	68084-0846-01
10254285	5704143	3901741	982033	Fluphenazine HCl Tablet	10 mg	100 UD	68084-0950-01
10252050	5688189	1584887	921783	Gabapentin Capsule	100 mg	100 UD	60687-0580-01
10252051	5688197	1584903	921791	Gabapentin Capsule	300 mg	100 UD	60687-0591-01
10252014	5688205	1584911	921817	Gabapentin Capsule	400 mg	100 UD	60687-0602-01
10254190	5703012	2302966	981886	Hydrochlorothiazide Tablet	25 mg	100 UD	60687-0593-01
10254966	5709282	2303436	45013	Ketorolac Tromethamine Tablet	10 mg	30 UD	60687-0104-21
10254154	5703616	3409216	42218	Lisinopril Tablet	2.5 mg	30 UD	68084-0765-21
10252801	5692983	1591213	944314	Levothyroxine Sodium Tablet	200 mcg	100 UD	60687-0552-01
10252199	5689559	1585892	922336	Mesalamine DR Capsule	400 mg	20 UD	60687-0556-32
10255420	5711163	2308062	19042	Prazosin HCl Capsule	5 mg	20 UD	60687-0572-32
10250600	5687215	1575356	927640	Propafenone HCl Tablet	150 mg	100 UD	60687-0537-01
10254155	5703574	3691490	981803	Rifampin Capsule	150 mg	30 UD	60687-0575-21
10254131	5703582	3693793	981845	Rifampin Capsule	300 mg	100 UD	60687-0586-01
10180508	5391024	3700200	075291	Tolterodine Tartrate ER Capsule	4 mg	30 UD	60687-0330-21

Liquid unit dose

AB 8-digit #	Cardinal Health #	McKesson #	Morris & Dickson #	Product description	Cup delivery	Cup strength	Pack size	NDC 11
10251651	5699970	3579828	971820	Milk of Magnesia Saline Laxative	30 mL	2400 mg/30 mL	100 ct	60687-0429-76

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Discontinued Drugs

Continued from Page 10

Diflorasone Diacetate Ointment 0.05% By Teligent

On July 6, 2021, the FDA announced that Teligent Pharma, Inc. of Buena, New Jersey will discontinue the manufacture of Diflorasone Diacetate Ointment 0.05%, in the following tube presentations.

- **15Gm:** NDC #52565-063-15.
- **30Gm:** NDC #52565-063-30.
- **60Gm:** NDC #52565-063-60.

This product is indicated for the treatement of eczema or psoriasis.

Fluocinonide Gel 0.05% By Teligent Pharma

On June 21, 2021, the FDA announced that Teligent Pharma, Inc. of Buena, New Jersey will discontinue the manufacture of Fluocinonide Gel 0.05%, in the following tube presentations.

- **15Gm:** NDC #52565-054-15.
- **30Gm:** NDC #52565-054-30.
- **60Gm:** NDC #52565-054-60.

This product is a corticosteroid indicated to treat inflammation and itching caused by plaque psoriasis and skin conditions that respond to steroid medication.

Fluocinonide Ointment 0.05% By Teligent Pharma

On June 21, 2021, the FDA announced that Teligent Pharma, Inc. of Buena, New Jersey will discontinue the manufacture of Fluocinonide Ointment 0.05%, in the following tube presentations.

- **15Gm:** NDC #52565-040-15.
- **30Gm:** NDC #52565-040-30.
- **60Gm:** NDC #52565-040-60.

This product is a corticosteroid indicated to treat inflammation and itching caused by plaque psoriasis and skin conditions that respond to steroid medication.

Metoclopramide 10mg Tablets By Par Pharmaceutical

On July 6, 2021, the FDA announced that Par Pharmaceutical, Inc. of Chestnut Ridge, New York has made a business decision to discontinue the manufacture of Metoclopramide 10mg Tablets in two different bottle sizes, as follows.

- **100-count bottles:** NDC #49884-0689-01.
- **500-count bottles:** NDC #49884-0689-05.

This product is indicated to treat heartburn caused by gastroesophageal reflux in people who have used other medications without relief. It is also used to treat gastroparesis (slow stomach emptying) in people with diabetes, which can cause heartburn and stomach discomfort after meals.

Moxeza™ Ophthalmic Solution

On July 2, 2021, the FDA announced that Novartis Pharmaceuticals Corporation of East Hanover, New Jersey has made a business decision to permanently discontinue the manufacture of Moxeza™ (moxifloxacin) Ophthalmic Solution 5mg/mL, in 3mL bottles (NDC #0065-0006-03).

This product is indicated for the treatment of bacterial infections in the eyes.

Muse® Suppository

On June 14, 2021, the FDA announced that Mylan Pharmaceuticals Inc. of Canonsburg, Pennsylvania (now a Viatris Inc. company) will discontinue the manufacture of Muse® (alprostadil) Suppository 125mcg in 6 single-dose packages (NDC #0037-8110-06).

This product is indicated to treat erectile dysfunction (ED).

Tizanidine HCl Capsules By Endo

On June 30, 2021, the FDA announced that Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania (with labeling by Par Pharmaceutical) will discontinue the manufacture of Tizanidine HCl Capsules, in the following strengths.

- **2mg:** NDC #49884-611-53.
- **4mg:** NDC #49884-719-53.
- **6mg:** NDC #49884-765-53.

This product is indicated to treat spasticity by temporarily relaxing muscle tone.

Vancomycin HCl Injection By Viatris

On July 26, 2021, the FDA announced that Mylan Institutional Inc. of Rockford, Illinois, a Viatris company, will discontinue the manufacture of Vancomycin HCl Injection Lyophilisate Sterile Powder 250mg in 10 single-dose vial packs, (NDC #67457-822-99).

This product is and antibiotic indicated to treat certain serious infections such as endocarditis (infection of the heart lining and valves), peritonitis (inflammation of the lining of the abdomen), and infections of the lungs, skin, blood, and bones.

Zocor® Tablets

On July 27, 2021, the FDA announced that Merck Sharp & Dohme Corp. of Kenilworth, New Jersey will discontinue the manufacture of Zocor® (simvastatin) Tablets 80mg, in 30-count and 90-count bottles (NDC #0006-0543-31 and NDC #0006-0543-54 respectively).

Simvastatin is indicated to lower blood levels of "bad" cholesterol, increase levels of "good" cholesterol, and to lower triglycerides (a type of fat in the blood). It is also used to lower the risk of stroke and heart complications in people with diabetes, coronary heart disease, or other risk factors.

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Magnets In Certain Cell Phones...

Continued from Page 1

a defibrillator's lifesaving functions, and this research indicates the urgency for everyone to be aware that electronic devices with magnets can interfere with cardiac implantable electronic devices."

An internal pacemaker (a small device that uses electric stimulation to help keep the heart beating regularly) is surgically placed just under the skin and connected to the heart with tiny wires. An implantable cardioverter defibrillator is a device also placed under the skin and attached to the heart so that if an abnormal heart rhythm is detected it can initiate a small electric shock to restore a normal heartbeat. Both types of devices offer therapeutic and lifesaving solutions for people with specific cardiac conditions such as arrhythmia, congenital heart disease, or deterioration of the heart muscle due to age. Each year in the U.S., more than 50,000 patients, 65 years of age and older, receive implantable cardioverter defibrillators.

While the electromagnetic waves of some portable electronics and machinery can interfere with how implantable cardiac devices operate, before now, modern cell phones had been found to pose little risk.

In the new study, researchers tested 14 different cardiac implantable electronic devices made by 3 major manufacturers to investigate if the magnetic components of the iPhone 12 Pro Max would affect how the devices work. Three of the cardiac devices tested were implanted in a patient and were tested through the patient's skin. The remaining 11 cardiac devices were new and still in the manufacturers' packaging. Each device was first tested using a donut magnet to evaluate if magnet mode (the mode activated by healthcare professionals to change the device functioning or turn it off) was achievable.

For the 3 implanted devices, the iPhone 12 Pro Max was placed directly on the skin over the cardiac device to check for activation of magnet mode. For the new cardiac devices still in packages, wireless connection was established with each, and the iPhone 12 Pro Max was placed within 1.5cm directly over the cardiac device still in the sealed manufacturer's package.

Clinically identifiable magnetic interference was detected in all 3 of the implanted devices, and in about three quarters (8 of the 11) of the new, in-the-package cardiac devices. All interference was triggered by the proximity of the series 12 iPhone; no other magnetic devices were near. In total, 11 of the 14 devices (79%) experienced malfunctioning when within 1.5cm of the iPhone 12 Pro Max.

N.A. Mark A. Estes, M.D., Professor of Medicine and Director of the Clinical Cardiac Electrophysiology Fellowship Program at the Heart & Vascular Institute of the University of Pittsburgh School of Medicine in Pennsylvania, said: "The American Heart Association and manufacturers of pacemakers and implantable cardioverter defibrillators have long recommended that cell phones be used in the ear opposite the side of the body of an implanted device, and that the cell phones be kept at least 10cm away from the device, therefore not in a shirt or coat pocket on the same side as the cardiac device. While the risk from temporary interference was only tested with specific devices and cell phones, the AHA reminds people with cardiac implantable electronic devices to remain informed of the latest FDA guidance for their heart device, the manufacturers' safety guidelines, and to contact their healthcare professional with any questions or concerns."

Precautions for Patients with Pacemakers & Other Implanted Medical Devices: the FDA recommends people with implanted medical devices may want to take some simple precautions, such as the following.

- Keep the consumer electronics, such as certain cell phones and smart watches, 6 inches away from implanted medical devices.
- Do not carry consumer electronics in a pocket over the medical device.
- Check your device using your home monitoring system, if you have one.
- Talk to your healthcare provider if you are experiencing any symptoms or have questions regarding magnets in consumer electronics and implanted medical devices.
- When near high strength magnets, devices with a magnetic safe mode could stop working or change how the device works. For example, a cardiac defibrillator may be unable to detect tachycardia events. Or it may change the operational mode of the devices such as turning on asynchronous (i.e., 2 or more events not happening at the same time) mode in a pacemaker.

Jeff Shuren, M.D., J.D., Director of the FDA's Center for Devices & Radiological Health, stated: "Ensuring the safety of our nation's medical devices is a cornerstone of our consumer protection mission, especially as technology continues to advance. As part of this work, the agency reviewed recently published articles describing the possibility that certain newer cell phones, smart watches, and other consumer electronics with high field strength magnets may temporarily affect the normal operation of implanted electronic medical devices, such as pacemakers and implantable defibrillators. Based on our review, we decided to conduct our own testing to confirm and help inform appropriate recommendations for patients and consumers. As a result of these actions, we're taking steps to

Continued on Page 14

Novel Device To Protect Athletes' Brains During Head Impacts

On February 26, 2021, Q30 Sports Science, LLC of Westport, Connecticut (a division of Q30 Innovations, LLC) announced the FDA has authorized marketing of their non-invasive device called Q-Collar®, which is intended to be worn around the neck of athletes aged 13 years and older during sports activities for up to 4 hours at a time, to aid in the protection of the brain from the effects associated with repetitive sub-concussive head impacts.

The device is a C-shaped collar that applies compressive force to the neck and increases blood volume to help reduce movement of the brain within the cranial space which may occur during head impacts. It may reduce the occurrence of specific changes in the brain that are associated with brain injury.

Christopher M. Loftus, M.D., Acting Director of the Office of Neurological & Physical Medicine Devices in the FDA's Center for Devices & Radiological Health, noted: "This device approval provides an additional piece of protective equipment athletes can wear when playing sports to help protect their brains from the effects of repetitive head impacts while still wearing the personal protective equipment associated with the sport."

Traumatic brain injury (TBI) can be caused by a forceful bump, blow, or jolt to the head or body, or from an object that pierces the skull and enters the brain. Not all blows or jolts to the head result in a TBI. From 2006 to 2014, the number of TBI-related emergency department visits, hospitalizations, and deaths increased by 53%, according to the U.S. Centers for Disease Control & Prevention (CDC). Blunt trauma accidents, or accidents that involve being struck by or against an object, particularly sports-related injuries, are a major cause of TBI. The National Institute of Neurological Disorders & Stroke notes that anywhere from 1.6 million to 3.8 million sports and recreation-related TBI's are estimated to occur in the United States annually.

When worn around the neck during sports activities, the Q-Collar provides compressive force to the internal jugular veins, which in turn increases the blood volume in the skull's blood vessels. Typically, when people experience blunt trauma accidents, the brain moves unrestrained in the skull, which is known as a "slosh." The Q-Collar's increase in blood volume in those blood vessels creates a tighter fit of the brain inside the skull and reduces the "slosh" movement. By reducing the movement of the brain within the cranial space, the Q-Collar may aid in the protection of the brain from the effects of head impacts.

The FDA assessed the safety and effectiveness of the Q-Collar through several studies, including a prospective, longitudinal study in the United States with 284 subjects 13 years or older who were participants on a high school football team. During the sports season, 139 athletes wore the Q-Collar and 145 athletes did not. All participants also wore an accelerometer device that measured every impact to the head sustained during play. Each athlete underwent a magnetic resonance imaging (MRI) scan pre-season and post-season. These MRI scans were used to generate Diffusion Tensor Imaging (a specialized MRI image) of the brain that allowed researchers to compare structural changes in the participants' brain, after a season of play.

Significant changes were found in deeper tissues of the brain involved in the transmission of electrical nerve signals (white matter regions) in 106 of the 145 (73%) participants in the no-Collar group, while no significant changes in these regions were found in 107 of the 139 (77%) of the group who wore the Q Collar. These differences appear to indicate protection of the brain associated with device use. No significant adverse events were associated with device use.

The device should be replaced after 2 years of active use or upon the product's expiration date listed on the package (whichever comes first). Q-Collar is intended for over-the-counter (OTC) use, and will be distributed directly to consumers. However, a medical

Continued on Page 29

Magnets In Certain Cell Phones...

Continued from Page 13

provide information for patients and healthcare providers to ensure they are aware of potential risks and can take simple proactive and preventative measures. We believe the risk to patients is low and the agency is not aware of any adverse events associated with this issue at this time. However, the number of consumer electronics with strong magnets is expected to increase over time. Therefore, we recommend people with implanted medical devices talk with their healthcare provider to ensure they understand this potential risk and the proper techniques for safe use."

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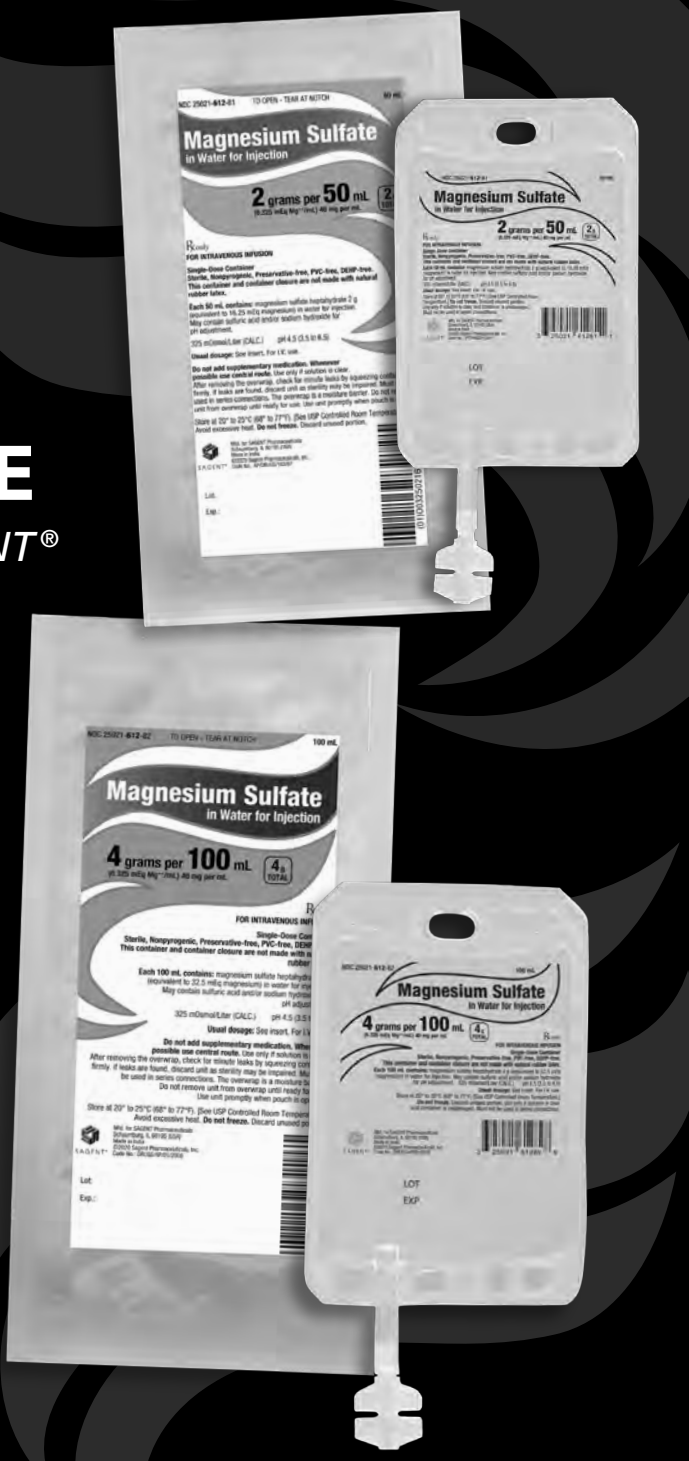

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New Drugs/Indications

Aduhelm™ Injection - First & Only Alzheimer's Disease Treatment To Address Disease's Defining Pathology

On June 7, 2021, Biogen Inc. of Cambridge, Massachusetts and Eisai Inc. of Woodcliff Lake, New Jersey jointly announced the FDA approval of Aduhelm™ (aducanumab-avwa) Injection for intravenous (IV) use; indicated as the first and only Alzheimer's disease treatment to address a defining pathology of the disease by reducing amyloid beta plaques in the brain.

Aduhelm Injection represents a first of its kind treatment approved for Alzheimer's disease. It is the first new treatment approved for Alzheimer's since 2003, and is the first therapy that targets the fundamental pathophysiology of the disease.

Alzheimer's is an irreversible, progressive brain disorder that slowly destroys memory and thinking skills, and eventually, the ability to carry out simple tasks. While the specific causes of Alzheimer's disease are not fully known, it is characterized by changes in the brain, including amyloid plaques and neurofibrillary or tau, tangles; that result in loss of neurons and their connections. These changes affect a person's ability to remember and think.

George Vradenburg, Chairman & Co-Founder of Us Against Alzheimer's in Washington, D.C., noted: "This approval of Aduhelm is a transformational breakthrough in the fight to stop this horrible disease. After years of disappointment and despair, this decision offers new hope for many families and a trigger for future investment and innovation. Because Aduhelm was studied in people with early-stage Alzheimer's disease, it will be important for our nation's healthcare system, patients, providers, and payers to be ready for earlier detection, diagnosis, and intervention in the treatment of the disease."

Biogen licensed Aduhelm from Neurimmune AG of Schlieren, Switzerland in 2007, under a collaborative development and license agreement. Since October 2017, Biogen and Eisai have collaborated on the development and commercialization of Aduhelm globally.

The FDA granted Aduhelm with Fast Track designation, and Accelerated Approval, which can be used for a drug for a serious or life-threatening illness that provides a meaningful therapeutic advantage over existing treatments.

Patrizia Cavazzoni, M.D., Director of the FDA's Center for Drug Evaluation & Research, said: "Alzheimer's disease is a devastating illness that can have a profound impact on the lives of people diagnosed with the disease as well as their loved ones. Currently available therapies only treat symptoms of the disease; this treatment option is the first therapy to target and affect the underlying disease process of Alzheimer's. As we have learned from the fight against cancer, the Accelerated Approval pathway can bring therapies to patients faster while spurring more research and innovation."

Astepro® Allergy Nasal Spray - Rx-To-OTC Switch

On June 17, 2021, Bayer Healthcare LLC of Whippany, New Jersey announced that the FDA has approved for over-the-counter (OTC) use through a process called a "partial prescription to nonprescription switch": Astepro® Allergy (azelastine HCI) Nasal Spray 0.15%, now to be available over-the-counter (OTC). It is indicated for the temporary relief of nasal congestion, runny nose, sneezing, and itchy nose due to hay fever or other upper respiratory allergies.

Product will be available at national retail locations in the first quarter of 2022.

This OTC formulation is still at full prescription strength, and includes a number of benefits including flexible once or twice daily dosing that provides up to 24-hour relief of nasal congestion, running nose, sneezing, and itchy nose from indoor and outdoor allergies.

With this OTC availability, Astepro Allergy becomes the first and only steroid free, antihistamine nasal spray for allergies available OTC in the United States for adults and children 6 years of age and older. Before now, Astepro Allergy has only been available with a prescription in the United States.

Currently, OTC allergy medications includes 3 major classes: 1) antihistamines; 2) intranasal steroids; and 3) mast cell stabilizers. Astepro Allergy will be the first and only OTC antihistamine nasal spray for indoor and outdoor allergy relief upon the OTC switch.

This approval is a first-in-class switch for a nasal antihistamine and is considered a partial switch because the 0.1% strength, which includes the perennial allergy indication for children 6 months to 6 years old and seasonal allergy indication for children 2 to 6 years old, will remain prescription based.

Theresa M. Michele, M.D., Director of the Office of Nonprescription Drugs in the FDA's Center for Drug Evaluation & Research (CDER), said: "Seasonal and perennial allergies affect millions of Americans every year, causing them to experience symptoms of nasal congestion, runny nose, sneezing, and more. This approval provides individuals an option for a safe and effective nasal antihistamine without requiring the assistance of a healthcare provider."

Epclusa® For Chronic Hepatitis C - New Oral Pellet Formulation

On June 10, 2021, Gilead Sciences, Inc. of Foster City, California announced the FDA has approved a New Drug Application (NDA) for 2 strengths of a ***new Oral Pellets formulation***

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New Drugs/Indications

Continued from Page 16

of Epclusa® (sofosbuvir/velpatasvir), as follows: 150mg/37.5mg, and 200mg/50mg. The new oral pellet formulation was developed for use by younger children who cannot swallow tablets.

In addition, the FDA also ***expanded the approval*** of Epclusa Tablets & Oral Pellets, to now include children as young as 3 years of age, for the treatment of chronic hepatitis C virus, regardless of the hepatitis C virus genotype or liver disease severity.

This product is the only protease inhibitor-free, pangenotypic hepatitis C virus (HCV) regimen approved for patients as young as 3 years of age, and recommended dosages are based on weight.

Merdad Parsey, M.D., Ph.D., Chief Medical Officer of Gilead Sciences, said: "Gilead remains steadfast in our commitment to supporting HCV elimination. This decision by the FDA represents important progress toward that goal by expanding more cure options for children living with HCV. This approval adds to the robust clinical evidence supporting the safety and efficacy of Epclusa across a broad set of patients, including those with end-stage renal disease and all stages of fibrosis."

As of 2018 in the U.S., there were approximately 35,300 to 60,500 children living with HCV; and incidences have been on the rise since that time. Mother-to-child transmission (the most common cause of HCV infection in children), increased 161% from 2009 to 2017, with intravenous drug use representing the primary driver of HCV infection among women of childbearing age.

Karen Murray, M.D., Chair of Cleveland Clinic Children's (and lead investigator of the drug's pediatric study), said: "Treating pediatric HCV remains an important public health priority. The Phase 2 clinical trial results previously showed that this medication was effective in treating many HCV-infected patients, regardless of genotype. Now, the expanded approval and oral pellet formulation offer new treatment strategies in younger patients with HCV."

Epclusa is indicated for the treatment of adults and pediatric patients (3 years of age and older) with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis and in combination with ribavirin for those with decompensated cirrhosis.

Exservan™ Oral Film For ALS (First Film Formulation Of Riluzole) - Now Available

On June 30, 2021, Mitsubishi Tanabe Pharma America, Inc. of Jersey City, New Jersey announced that Exservan™ (riluzole), the first oral film formulation of riluzole, is now available in the U.S. for the treatment of amyotrophic lateral sclerosis.

The recommended dosage for Exservan film is 50mg dissolved on the top of the tongue, taken twice a day without liquids or food. It should be taken at least 1 hour before or 2 hours after a meal. After placing the film on the tongue, swallow in a normal manner, do not cut or split the film or take liquids with it, nor chew, spit, or talk while it is dissolving.

Exservan was developed to help meet the needs of people with amyotrophic lateral sclerosis (ALS), including those who have difficulty swallowing some medications.

ALS is a progressive nervous system disease that affects nerve cells in the brain and spinal cord, causing loss of muscle control, and also impacting general physical function. It is often called Lou Gehrig's disease, after the baseball player who was diagnosed with it. Doctors usually don't know why ALS occurs, although some cases are inherited. ALS often begins with muscle twitching and weakness in a limb, or slurred speech. Eventually, ALS affects control of the muscles needed to move, speak, eat, and breathe. Medication and therapy can slow ALS and reduce discomfort, but there is no cure for this fatal disease.

Atsushi Fujimoto, President of Mitsubishi Tanabe, said: "People with ALS can develop difficulty swallowing, affecting how certain medications are administered. Patients are the primary focus of our work as we try to make a difference, and we are pleased to bring this new option to those suffering from this devastating and progressive disease."

Exservan was developed by Aquestive Therapeutics, Inc. of Warren, New Jersey, using its PharmFilm® innovative drug delivery technology. Under the terms of a licensing and supply deal agreement, Mitsubishi Tanabe is commercializing Exservan in the U.S., and Aquestive is serving as the exclusive sole manufacturer and supplier for the product.

The FDA approved Exservan oral film in November 2019, based on a pivotal bioavailability and bioequivalence study to bridge the safety and efficacy of the new oral film formulation to the approved tablet dosage form of riluzole. Exservan was shown to deliver a similar amount of medication throughout the bloodstream as the riluzole tablets. Riluzole was originally FDA-approved in 1995 for the treatment of ALS, and showed that the time to tracheostomy or death was longer for patients receiving riluzole tablets compared to placebo.

Gary L. Pattee, M.D., Neurologist and ALS Specialist based in Lincoln, Nebraska, commented: "Many people with ALS have or will experience difficulty swallowing some

Continued on Page 18

New Drugs/Indications

Continued from Page 17

medications. I have even heard of some patients crushing tablets to take their medicine. Alternative formulations of riluzole can play an important role in the treatment plan for people with ALS, including those who have difficulties swallowing some medications. This is exciting news for the ALS community."

Note: Access to Exservan is available through a single specialty pharmacy, PANTHERx Rare Pharmacy. Treatment with the medication is initiated by a healthcare provider (HCP) by submitting a Prescription & Enrollment Form to PANTHERx. Patients are then contacted by the specialty pharmacy to review insurance benefits and product dispensing. Patients prescribed Exservan through the Department of Veterans Affairs, the Department of Defense, other federal institutions, and certain integrated delivery networks do ***not*** need to coordinate via PANTHERx. Be sure to carefully read the "Instructions for Use" on how to properly take Exservan oral film.

Fentanyl Citrate Injection (C-II) Opioid Analgesic In 1mL Simplist® Ready-To-Administer Prefilled Syringe

On July 7, 2021, Fresenius Kabi USA, LLC of Lake Zurich, Illinois announced their ***launch*** of Fentanyl Citrate Injection 50mcg per 1mL in its proprietary Simplist® ready-to-administer prefilled syringe, the only 1mL presentation currently available in the United States.

The 50mcg per 1mL prefilled syringe is designed to support initiatives at hospitals nationwide to reduce waste and diversion and help ensure safe delivery of the medication by eliminating steps where errors can occur.

Fentanyl Citrate has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 2 (C-II) controlled drug substance. It is indicated as follows, for intravenous (IV) or intramuscular use.

- 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 an opioid analgesic supplement, in 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.

This product should be administered only by persons specifically trained in the use of IV anesthetics and management of the respiratory effects of potent opioids. Ensure that an opioid antagonist, resuscitative and intubation equipment, and oxygen are readily available.

Simplist Fentanyl ready-to-administer prefilled syringes come in Fresenius Kabi's proprietary MicroVault® packaging system that also supports secure dispensing of narcotics and reduces the opportunity for diversion. Because the syringes require no assembly, they streamline point-of-care preparation. The presentation reduces the potential for product waste and makes it easier for healthcare professionals to dispense the prescribed dose.

Fresenius Kabi's Simplist prefilled syringes were associated with an error rate that was 4 times lower when compared to traditional medication administration practice, according to a study published in the *Journal of Patient Safety* in 2018. It is manufacturer-prepared in the United States, with a 24-month shelf life, and is a single-unit dose, supporting best practices for medication administration.

John Ducker, President & CEO of Fresenius Kabi, stated: "The introduction of an exclusive smaller-dose Fentanyl Injection is an important expansion of our Simplist ready-to-administer prefilled syringe portfolio in line with our commitment to the secure dispensing of controlled substances for the safe delivery of drugs to patients. We are proud to design, develop, and introduce products and labeling that support the safe dispensing of controlled substances, and all products."

Kerendia® For Chronic Kidney Disease Associated With Type 2 Diabetes

On July 9, 2021, Bayer USA of Whippany, New Jersey announced the FDA approval of Kerendia® (finerenone), a first-in-class non-steroidal mineralocorticoid receptor antagonist (MRA), indicated to reduce the risk of sustained eGFR decline, kidney failure, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes.

Product is expected to be available within 4 weeks of this announcement date.

Kevin Longino, CEO of the National Kidney Foundation (and kidney transplant patient), said: "Chronic kidney disease associated with type 2 diabetes can have such a debilitating impact on patients' lives. Unfortunately, this disease is far reaching, as up to 40% of all patients with type 2 diabetes develop chronic kidney disease. It is important for physicians and patients to have new treatment options that can slow chronic kidney disease progression."

New Drugs/Indications

Continued from Page 18

Despite guideline-directed therapies, many people with chronic kidney disease (CKD) associated with type 2 diabetes (T2D) are at risk for CKD progression and cardiovascular events. Type 2 diabetes is the leading cause of end stage kidney disease, when patients may need dialysis or a kidney transplant to stay alive. Blacks or African Americans and Hispanic Americans have higher rates of kidney failure than their non-Hispanic white counterparts.

Kerendia works by blocking overactivation of the mineralocorticoid receptor (MR). Mineralocorticoid receptor overactivation is thought to contribute to fibrosis and inflammation. Fibrosis and inflammation can contribute to permanent structural kidney damage.

The FDA granted Kerendia with Priority Review designation.

Amit Sharma, M.D., Bayer U.S. Medical Affairs VP of Cardiovascular & Renal Division, said: "Kerendia is the first and only nonsteroidal mineralocorticoid receptor antagonist proven to significantly slow chronic kidney disease progression and reduce cardiovascular risk in people with chronic kidney disease associated with type 2 diabetes. We are excited to bring this new kidney-focused treatment to people living with this condition."

Note: women should avoid breastfeeding during treatment with Kerendia and for 1 day after treatment.

Pradaxa® Oral Pellets - First Oral Blood Thinning Medication For Children

On June 21, 2021, the FDA announced their approval of Pradaxa® (dabigatran etexilate) Oral Pellets, indicated to treat children ages 3 months to younger than 12 years old with venous thromboembolism (a condition where blood clots form in the veins) directly after they have been treated with a blood thinner given by injection for at least 5 days; as well as to prevent recurrent clots among patients 3 months less than 12 years old who completed treatment for their first venous thromboembolism.

Additionally, Pradaxa was also approved in capsule form to treat blood clots in patients ages 8 years and older with venous thromboembolism directly after they have been treated with a blood thinner given by injection for at least 5 days; and also to prevent recurrent clots in patients 8 years and older who completed treatment for their first venous thromboembolism.

Pradaxa is the first FDA-approved blood thinning medication that children can take by mouth; the only other approved blood thinning medication for children is given by injection. Pradaxa was originally approved in 2010 to reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation.

Blood clots can be a serious problem in children as well as adults. Children are most at risk for blood clots if they have cancer, congenital heart disease, a central venous catheter, or are admitted to an intensive care unit. Venous thromboembolism can lead to complications, including swelling and discomfort near the clot, chest pain, lung damage, and even death.

Ann Farrell, M.D., Director of the Division of Non-Malignant Hematology in the FDA's Center for Drug Evaluation & Research (CDER), stated: "The FDA is committed to helping our youngest patients with serious medical conditions have treatments that are relatively easy to take. With this approval of Pradaxa, pediatric patients have another therapeutic option to treat and prevent potentially deadly blood clots."

Rylaze™ For Acute Lymphoblastic Leukemia Or Lymphoblastic Lymphoma

On June 30, 2021, Jazz Pharmaceuticals plc of Dublin, Ireland (with U.S. office in Palo Alto, California) announced that the FDA approved Rylaze™ (asparaginase *erwinia chrysanthemi*, recombinant-rywn) Injection for intramuscular use, indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia or lymphoblastic lymphoma in pediatric and adult patients 1 month and older, who have developed hypersensitivity to *E. coli*-derived asparaginase.

Product is expected to be available within 2 weeks from this announcement date.

Before now, the only other FDA-approved drug for such patients with allergic reactions has been in global shortage for years.

Acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) is a cancer of the blood and bone marrow that can progress quickly if not treated. Leukemia is the most common cancer in children, and about 3 out of 4 of these cases are ALL. Although it is one of the most common cancers in children and is among the most curable of the pediatric malignancies due to recent advancements in treatment. Adults can also develop ALL, and about 4 of every 10 cases diagnosed are in adults. The American Cancer Society estimates that almost 6,000 new cases of ALL will be diagnosed in the United States in 2021.

Asparaginase is a core component of multi-agent chemotherapeutic regimens in ALL. However, asparaginase treatments derived from *E. coli* are associated with the potential for development of hyper-sensitive reactions. Rylaze is the only recombinant *erwinia* asparaginase drug when manufactured that still

Continued on Page 20

New Drugs/Indications

Continued from Page 19

maintains a clinically meaningful level of asparaginase activity throughout the entire duration of treatment. It was developed by Jazz to address the needs of patients and healthcare providers with an innovative, high-quality *erwinia*-derived asparaginase with reliable supply.

Luke Maese, D.O., Assistant Professor at University of Utah and osteopathic physician at Primary Children's Hospital and the Huntsman Cancer Institute in Salt Lake City, said: "The accelerated development and approval of Rylaze marks an important step in bringing a meaningful new treatment option for many ALL patients, most of whom are children, who cannot tolerate *E. coli*-derived asparaginase medicine. Before the approval of Rylaze, there was a significant need for an effective asparaginase medicine that would allow patients to start and complete their prescribed treatment program with confidence in supply."

Recent data from a Children's Oncology Group retrospective analysis of over 8,000 patients found that patients who did not receive a full course of asparaginase treatment due to associated toxicity had significantly lower survival outcomes, regardless of whether those patients were high risk or standard risk, slow early responders.

The FDA granted Rylaze with Fast Track and Orphan Drug designations for this indication, and under the Real-Time Oncology Review (RTOR) program, an initiative of FDA's Oncology Center of Excellence designed for efficient delivery of safe and effective cancer treatments to patients. It was also conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence that provides a framework for concurrent submission and review of oncology drugs among international partners.

Gregory Reaman, M.D., Associate Director for Pediatric Oncology in the FDA's Oncology Center of Excellence, said: "It is extremely disconcerting to patients, families, and providers when there is a lack of access to critical drugs for treatment of a life-threatening, but often curable cancer, due to supply issue. This approval may provide a consistently sourced alternative to a pivotal component of potentially curative therapy for children and adults with this type of leukemia."

Note: Rylaze can harm an unborn baby. Women of reproductive potential should use effective contraception (other than oral contraceptives) during treatment and for 3 months following the final dose. Also, women should not breastfeed while receiving Rylaze and for 1 week after the final dose.

Ryplazim® - First Treatment For Plasminogen Deficiency

On June 4, 2021, Liminal BioSciences Inc. of Quebec, Canada announced that the FDA has approved Ryplazim® (plasminogen, human-tvmh) lyophilized powder for reconstitution (for intravenous use), indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenia).

The approval was given through Liminal's subsidiary Prometic Biotherapeutics Inc. of Rockville, Maryland as holder of the product's biological license application.

With this approval, Ryplazim becomes the first FDA approved therapy for this rare genetic disorder.

In all patients with plasminogen deficiency, plasma plasminogen levels are markedly reduced. Plasminogen is a naturally occurring protein that is synthesized by the liver and circulates in the blood. Activated plasminogen, known as plasmin, is an enzymatic component of the fibrinolytic system and the main enzyme involved in the lysis of clots and clearance of extravasated fibrin.

Patrick Sartore, President of Liminal BioSciences, said: "Ryplazim's approval gives patients and families who live with plasminogen type 1 deficiency a new option to try to manage symptoms. This marks an important turning point, providing a first and much-needed therapy for patients with this rare genetic disease."

The FDA granted Ryplazim with Fast Track Priority Review, Orphan Drug designation, and a Rare Pediatric Disease Priority Review Voucher, which is intended to encourage development of new drugs and biologics to prevent and/or treat rare diseases in children.

Peter Marks, M.D., Ph.D., Director of FDA's Center for Biologics Evaluation & Research, said: "Until now, there were no FDA-approved treatment options for patients with plasminogen deficiency type 1.

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New Drugs/Indications

Continued from Page 20

This approval helps address an unmet medical need for individuals affected by this rare genetic disease."

As part of the sale of Liminal's plasma collection centers operated in Manitoba, Canada and Amherst, New York in May 2021, Liminal entered into an option agreement with Kedrion Biopharma, pursuant to which Kedrion has the right to acquire the remainder of Liminal's plasma-derived therapeutics' business including the Ryplazim business, and would entitle Liminal to receive up to 70% of the net proceeds which may be received from the sale of a Rare Pediatric Disease Priority Review Voucher.

Tembexa® To Treat Smallpox

On June 4, 2021, Chimerix, Inc. of Durham, North Carolina announced that the FDA has granted approval for Tembexa® (brincido-fovir) Tablets and Oral Suspension, indicated for the treatment of smallpox in adult and pediatric patients, including neonates (infants less than 4 weeks old).

Tembexa is an oral antiviral formulated as 100mg tablets and 10mg/mL oral suspension dosed once weekly for 2 weeks. Tembexa is indicated for the treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates.

Smallpox is a highly contagious disease caused by the variola virus. Historically, smallpox was one of the deadliest diseases in history with a case fatality rate of approximately 30%. Despite successful eradication of smallpox in the 1970's, there is considerable concern that variola virus could reappear, either through accidental release or as a weapon of bioterrorism. According to the U.S. Centers for Disease Control & Prevention (CDC), variola virus is ranked in the highest risk category for bioterrorism agents (Category A) due to its ease of transmission, high mortality rate, and potential to cause public panic and social disruption.

Chimerix developed Tembexa oral formulations as medical countermeasures for the treatment of smallpox under an ongoing collaboration with the Biomedical Advanced Research & Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness & Response within the U.S. Department of Health & Human Services (HHS).

The FDA granted Tembexa with Priority Review, Fast Track, and Orphan Drug designations.

Mike Sherman, CEO of Chimerix, said: "We are delighted to report our first FDA approved products for the treatment of smallpox, particularly as the importance of pandemic preparedness has been put into focus over the last year. With this approval in hand, we now look forward to advancing our discussions with BARDA toward a procurement contract to support national preparedness."

Note: Tembexa may cause fetal harm when administered to pregnant women.

Wegovy™ - First & Only Once-Weekly Therapy For Weight Management

On June 4, 2021, Novo Nordisk USA of Plainsboro, New Jersey announced that the FDA has approved Wegovy™ (semaglutide) Injection for subcutaneous use (under-the-skin), 2.4mg once weekly, for chronic weight management in adults with obesity or overweight with at least one weight-related condition (such as high blood pressure, type 2 diabetes, or high cholesterol).

Product is now available.

This is the ***first-and-only*** prescription weight-loss medication approved with once-weekly dosing. In addition, it is the first approved drug for chronic weight management in adults with general obesity or overweight since 2014.

Wegovy is used with a reduced calorie meal plan and increased physical activity indicated for adults with obesity (BMI 30 or more) or overweight (BMI 27 or more) who also have weight related medical problems to help them lose weight and keep the weight off.

Obesity is recognized as a chronic disease and health issue by leading health organizations, including the American Medical Association, the U.S. Centers for Disease Control & Prevention (CDC), the Obesity Society, and the World Obesity Federation, among other global organizations.

Obesity is a chronic, progressive, and misunderstood disease that requires long term medical management. It has many contributing factors, including genetics, lifestyle, and environment. One key misunderstanding is that this is a disease of willpower, when in fact there is underlying biology that prevents people from losing weight and keeping it off. Obesity is influenced by a variety of factors, including genetics, appetite signals, behavior, and the environment.

Obesity is a gateway disease, associated with at least 60 other health conditions. The current COVID-19 pandemic has highlighted that obesity also increases the risk for severe illness and hospitalization due to COVID-19. The global increase in the prevalence of obesity is a public health issue that has severe cost implications to healthcare systems.

Continued on Page 24

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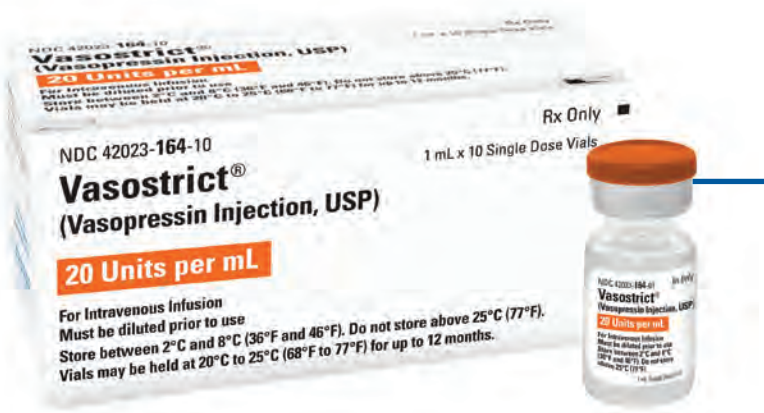

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42023-164-25	20 units/mL	1 mL SDV*	25	10145143	5033428	3424330	913442	
42023-190-01	20 units/mL	10 mL MDV**	1	10173721	5324769	3626108	884478	(01)00342023190017

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New Drugs/Indications

Continued from Page 21

In the United States, more than 42% of adults live with obesity.

Joe Nadglowski, President & CEO of the Obesity Action Coalition of Tampa, Florida, commented: "It's remarkable that obesity is still seen as a personal flaw rather than a medical condition requiring treatment, just like any other chronic disease. This disease can negatively impact one's quality of life, both through societal weight bias and stigma, as well as its association with numerous serious health issues. It's time that we recognized this national public health crisis and the need for as many tools as possible to address it. Expanding safe and clinically effective treatment options for obesity management is good news for people with obesity and the medical community."

Wegovy works by mimicking a hormone called glucagon-like peptide-1 (GLP-1) that targets areas of the brain that regulate appetite and food intake. The medication dose must be increased gradually over 16 to 20 weeks to 2.4mg once weekly to reduce gastrointestinal side effects.

Robert Kushner, M.D., Professor of Medicine & Medical Education at Northwestern University, Feinberg School of Medicine in Chicago, Illinois, said: "This is the first time we have seen this magnitude of weight loss with a medicine. This approval gives people with obesity a once-weekly, non-surgical option with results that have never been demonstrated with an anti-obesity medicine before. The approval of Wegovy represents a turning point for healthcare providers to embrace medical management of obesity to help improve chronic weight management for patients."

Note: women are advised to stop using Wegovy 2 months before planning to become pregnant. In addition, it should not be used in combination with other semaglutide-containing products, other GLP-1 receptor agonists, or other products intended for weight loss, including prescription drugs, over-the-counter drugs, or herbal products.

Zynrelef™ ER For Postoperative Pain Up To 72 Hours - Now Available

On July 1, 2021, Heron Therapeutics, Inc. of San Diego, California announced that Zynrelef™ ER Solution (bupivacaine/meloxicam extended release) is ***now available*** at all national wholesalers and the largest U.S. specialty distributors; after receiving its FDA approval in early May *(see May 2021 PPO).*

Zynrelef is indicated for use in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty.

Barry Quart, Pharm.D., Chairman & CEO of Heron, said: "We are pleased that Zynrelef is now available for ordering at hospitals and ambulatory surgical centers (ASC's) across the United States, as the first and only ER dual-acting local anesthetic. Zynrelef is the only local anesthetic for postoperative pain designated by the FDA to be ER for up to 72 hours after surgery, which may help patients and healthcare providers reduce overreliance on opioids but also mitigate exposure to their unwanted side effects and the potential for long-term safety risks like opioid misuse, abuse, or addiction."

Heron's new acute care sales team has extensive operating room, postoperative pain, and hospital launch experience. The team has been meeting with key customers and has executed contracts for Zynrelef with the 2 largest group purchasing organizations, Vizient and Premier Inc.

Zynrelef delivers a fixed-dose combination of the local anesthetic bupivacaine and a low dose of the nonsteroidal anti-inflammatory drug (NSAID) meloxicam. The synergy between bupivacaine and meloxicam in Zynrelef has resulted in patients experiencing significantly less pain, including severe pain, and significantly more patients requiring no opioids (opioid-free) after surgery as compared to bupivacaine solution, the current standard-of-care.

Zynrelef is the first and only dual-acting local anesthetic (DALA) that delivers a fixed-dose combination of the local anesthetic bupivacaine and a low dose of meloxicam (NSAID). Zynrelef is the first modified-release local anesthetic to be classified by FDA as an "ER" product because Zynrelef is also the first and only ER local anesthetic to demonstrate in Phase 3 clinical studies significantly reduced pain and significantly increased proportion of patients requiring no opioids through the first 72 hours following surgery compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control.

New Drugs/Indications

Continued from Page 24

New Indications

Ayvakit™ Tablets For Advanced Systemic Mastocytosis

On June 16, 2021, Blueprint Medicines Corporation of Cambridge, Massachusetts announced the FDA has approved a ***new indication*** for Ayvakit™ (avapritinib) Tablets, now also for the treatment of adult patients with advanced systemic mastocytosis, including aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, and mast cell leukemia.

Product is available in the strengths of: 25mg, 50mg, 100mg, 200mg, and 300mg.

The recommended dose of Ayvakit in advanced systemic mastocytosis (SM) is 200mg once daily.

For the first time, advanced SM patients can now receive a targeted therapy designed to potently and selectively inhibit D816V mutant KIT, the central driver of the disease.

Valerie Slee, Board Chair of The Mast Cell Disease Society of Sterling, Massachusetts, explained: "People with advanced SM face a scary, uncertain future due to life-threatening complications of the disease, as well as debilitating symptoms that often profoundly alter their ability to perform daily activities, and the FDA approval of a new therapy, Ayvakit, brings much needed hope to these patients."

SM is a rare hematologic disorder caused by the KIT D816V mutation in nearly all cases. Uncontrolled proliferation and activation of mast cells result in chronic, severe, and often unpredictable symptoms for patients across the spectrum of SM. The vast majority of those affected have non-advanced (indolent or smoldering) SM, with debilitating symptoms that lead to a profound, negative impact on quality of life.

A minority of patients have advanced SM, which encompasses a group of high-risk SM subtypes including aggressive SM (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL). Across advanced SM subtypes, the median overall survival is approximately 3.5 years in ASM, approximately 2 years in SM-AHN, and less than 6 months in mast cell leukemia MCL. In addition to mast cell activation symptoms, advanced SM is associated with organ damage due to mast cell infiltration and poor survival.

Daniel DeAngelo, M.D., Ph.D., Chief of the Division of Leukemia at Dana-Farber Cancer Institute of Boston, Massachusetts, said: "Advanced SM is a debilitating disease characterized by extensive damage in multiple organ systems due to mast cell infiltration, and new treatment options are urgently needed to address these life-threatening complications. Ayvakit will clearly establish a new standard of care for patients with advanced SM. The FDA approval was based on data showing robust and durable responses, including complete remissions, and a favorable safety profile. For advanced SM patients, this approval shifts the treatment paradigm toward precision therapy that targets the primary driver of mastocytosis."

The FDA granted Ayvakit with Priority Review, Breakthrough Therapy, and Orphan Drug designations.

Note: Ayvakit can cause fetal harm when administered to a pregnant woman. Females and males of reproductive potential should use an effective method of contraception during treatment with Ayvakit and for 6 weeks after the final dose. Breastfeeding during treatment with Ayvakit is not advised and for 2 weeks after the final dose.

Bydureon BCise® For Type 2 Diabetes In Pediatric Patients 10 Years & Older

On July 23, 2021, AstraZeneca USA of Wilmington, Delaware announced that the FDA approved a ***new indication*** of Bydureon BCise® (exenatide extended-release) once-weekly Injectable Suspension, now also for the treatment of type 2 diabetes; to improve glycemic control in pediatric patients 10 to 17 years as an adjunct to diet and exercise.

This is the first regulatory approval for a once-weekly glucagon-like peptide-1 receptor agonist (GLP-1 RA) in this population; which is an important development in diabetes care for this specific group of patients, since the only non-insulin options for adolescents are metformin and liraglutide.

First approved in the U.S. in October 2017, Bydureon BCise initial indication was as a once-weekly single-dose autoinjector device for adults with type 2 diabetes whose blood sugar remains uncontrolled on one or more oral medicines in addition to diet and exercise, to improve glycemic control.

William Tamborlane, M.D., Department of Pediatrics at Yale School of Medicine of New Haven, Connecticut (and international coordinating investigator of the drug's trial study), said: "The FDA approval is an important milestone for the treatment of children with type 2 diabetes. Bydureon BCise brings an important new therapeutic option to physicians caring for children with this chronic disease that can lead to serious long-term issues if not adequately treated."

Continued on Page 26

New Drugs/Indications

Continued from Page 25

Dalvance® For Acute Bacterial Skin & Skin Structure Infections In Pediatric Patients

On July 23, 2021, AbbVie of North Chicago, Illinois announced that the FDA approved an ***expanded approval*** of Dalvance® (dalbavancin) Powder for Injection, via intravenous infusion use, now also for pediatric patients from birth, for the treatment of acute bacterial skin and skin structure infections.

Dalvance is the first single-dose option administered as a 30-minute intravenous (IV) infusion for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible Gram-positive bacteria in pediatric patients, including infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA).

ABSSSI are bacterial infections of skin and associated tissues primarily caused by Gram-positive pathogens, including *Staphylococcus aureus* and *Streptococcus pyogenes*. While ABSSSI are common, these infections can be serious and may be life-threatening, and are a significant source of morbidity in children. Cutaneous abscesses and cellulitis are the predominant types of skin infections evaluated by pediatricians. In the U.S., ABSSSI lead to 3 million pediatric healthcare visits per year, placing a heavy burden on the healthcare system.

The approved dosage regimen of Dalvance in pediatric patients with a creatinine clearance of 30mL/min/1.73m2 and above, is a single-dose regimen based on the age and weight of the pediatric patient.

Dalvance for injection is a second-generation, semi-synthetic lipoglycopeptide, which consists of a lipophilic side-chain added to an enhanced glycopeptide backbone. It is the first and only IV antibiotic approved for the treatment of ABSSSI with a single dose regimen of 1,500mg and two-dose regimen of 1,000mg followed one week later by 500mg in adults, and a single dose regimen based on age and weight in pediatric patients, each administered over 30 minutes. Dalvance demonstrates bactericidal activity *in vitro* against a range of Gram-positive bacteria such as *Staphylococcus aureus* (including methicillin-resistant-MRSA strains) and *Streptococcus pyogenes*, as well as certain other streptococcal species.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Dalvance and other antibacterial agents, it should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Margaret Burroughs, M.D., AbbVie Medical Director of Infectious Diseases, said; "Serious infections in children can be difficult to treat and the impact of ABSSSI among children is significant, as these infections often require IV antibiotics, resulting in hospitalization. This pediatric approval for Dalvance as a single-dose provides a meaningful contribution to the treatment of children and infants with ABSSSI."

Darzalex Faspro® + Pomalidomide & Dexamethasone For Multiple Myeloma After First Or Subsequent Relapse

On July 12, 2021, Janssen Pharmaceuticals, Inc. of Raritan, New Jersey (a Johnson & Johnson Company) announced that the FDA approved a ***new indication*** of Darzalex Faspro® (daratumumab/hyaluronidase-fihj) Injection for subcutaneous use in combination with pomalidomide and dexamethasone (Pd), now also for the treatment of adult patients with multiple myeloma who have received at least one prior line of therapy, including lenalidomide and a proteasome inhibitor.

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. When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow. In 2021, it is estimated that more than 34,000 people will be diagnosed and close to 12,500 will die from the disease in the United States. While some patients with multiple myeloma have no symptoms, most patients are diagnosed due to symptoms, which can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems, or infections.

Darzalex Faspro is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's Enhanze® drug delivery technology.

Continued on Page 28

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LEVETIRACETAM IN 0.75% SODIUM CHLORIDE	14789-0220-10	14789-0220-08	1000 mg/100 mL	10 by 100 mL IV Bags	10237513	1555960	5659511	906263
LEVETIRACETAM IN 0.54% SODIUM CHLORIDE	14789-0330-15	14789-0330-08	1500 mg/100 mL	10 by 100 mL IV Bags	10237476	1555978	5659529	906321

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New Drugs/Indications

Continued from Page 26

Meletios A. Dimopoulos, M.D., Professor and Chairman of the Department of Clinical Therapeutics at the National & Kapodistrian University of Athens School of Medicine in Greece (and principal investigator of the study), said: "Clinical studies have continued to show the ability of daratumumab-based combination treatment regimens to significantly reduce the risk of progression in patients with multiple myeloma. With this approval, we are now able to combine pomalidomide and dexamethasone with a daratumumab subcutaneous option that can be administered in minutes rather than the hours needed for intravenous administration."

In August 2012, Janssen Biotech, Inc., and Genmab A/S entered into a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture, and commercialize daratumumab.

Note: Darzalex Faspro can cause fetal harm when administered to a pregnant woman. Advise females with reproductive potential to use effective contraception during treatment and for 3 months after the last dose.

Keytruda® For Locally Advanced Cutaneous Squamous Cell Carcinoma

On July 6, 2021, Merck & Co., Inc. of Kenilworth, New Jersey announced that the FDA has approved an ***expanded indication*** for Keytruda® (pembrolizumab) Injection 100mg, now as monotherapy for the treatment of patients with locally advanced cutaneous squamous cell carcinoma that is not curable by surgery or radiation.

Vicki Goodman, M.D., VP of Clinical Research for Merck Research Laboratories, said: "This approval is great news for these patients and further demonstrates Merck's commitment to the skin cancer community. Keytruda has shown meaningful efficacy in patients with locally advanced or recurrent or metastatic cutaneous squamous cell carcinoma that cannot be cured by surgery or radiation. This expanded indication reinforces the role of Keytruda in this cancer type, which is the second most common form of non-melanoma skin cancer."

Keytruda is an anti-programmed death receptor-1 (PD-1) therapy that works by increasing the ability of the body's immune system to help detect and fight tumor cells. Keytruda is a humanized monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumor cells and healthy cells.

In June 2020, Keytruda was granted its first indication in cutaneous squamous cell carcinoma (cSCC), as monotherapy for the treatment of patients with recurrent or metastatic disease that is not curable by surgery or radiation.

Note: Keytruda can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use effective contraception during treatment and for 4 months after the last dose. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 4 months after the final dose.

Padcev® Injection For Locally Advanced Or Metastatic Urothelial Cancer

On July 9, 2021, Astellas Pharma US, Inc. of Northbrook, Illinois and Seagen, Inc. of Bothell, Washington jointly announced the FDA approved a ***new indication*** for Padcev® (enfortumab vedotin-ejfv) Injection for intravenous (IV) use, now for adult patients with locally advanced or metastatic urothelial cancer who are ineligible for cisplatin-containing chemotherapy and have previously received 1 or more prior lines of therapy.

Cisplatin-ineligible patients typically have limited treatment options and a poor prognosis.

The recommended dose of Padcev is 1.25mg/kg (up to a maximum dose of 125mg) administered as an IV infusion over 30 minutes on days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity.

Evan Y. Yu, M.D., Oncologist in the Department of Medicine at the University of Washington School of Medicine in Seattle (and lead investigator in the drug's clinical trial), noted: "Almost half of advanced bladder cancer patients cannot receive cisplatin-based chemotherapy. Many of these patients will receive first-line immunotherapy. If their cancer does not respond, or if it progresses after prior response to immunotherapy, there is an urgent need for more treatment options as there is currently no standard of care. A new regulatory approval for enfortumab vedotin is an important clinical advance and can help serve this unmet need."

Globally, approximately 573,000 new cases of bladder cancer and more than 212,000 deaths are reported annually. Padcev is the subject of a robust development program aimed at addressing unmet needs across the continuum of urothelial cancer and in other solid tumors.

Roger Dansey, M.D., Chief Medical Officer for Seagen, said: "Padcev is the first and only FDA-approved therapy for patients with locally advanced or metastatic urothelial cancer who have received immunotherapy and cannot receive cisplatin. Because of the FDA's Real-Time Oncology Review, we're able to make Padcev available as early as possible to these patients, who have limited treatment options due to their age or comorbid conditions."

Padcev is co-developed by Astellas and Seagen. It is a first-in-class antibody-drug conjugate that

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New Drugs/Indications

Continued from Page 29

is directed against Nectin-4, a protein located on the surface of cells and highly expressed in bladder cancer. Nonclinical data suggest the anticancer activity of Padcev is due to its binding to Nectin-4 expressing cells followed by the internalization and release of the anti-tumor agent monomethyl auristatin E (MMAE) into the cell, which result in the cell not reproducing (cell cycle arrest) and in programmed cell death (apoptosis).

Padcev was reviewed under the FDA's Real-Time Oncology Review (RTOR) pilot program, which aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible. The review was also conducted as part of Project Orbis, an initiative of the FDA Oncology Center of Excellence that provides a framework for concurrent submission and review of oncology drugs among participating international health authorities.

Note: advise female patients of reproductive potential to use effective contraception during Padcev treatment and for 2 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Padcev and for 4 months after the last dose. Additionally, women should not breastfeed during treatment with Padcev and for at least 3 weeks after the last dose.

Prograf® To Prevent Organ Rejection In All Lung Transplant Recipients

On July 20, 2021, Astellas Pharma US, Inc. of Northbrook, Illinois announced that the FDA has approved its supplemental New Drug Application (sNDA) for an ***expanded approval*** of Prograf® (tacrolimus) Capsules, Injection, and Suspension, now also for the prevention of organ rejection (liver, kidney, heart, or lung), in adult and pediatric lung transplant recipients.

Initially FDA-approved in 1994, Prograf is a calcineurin inhibitor immunosuppressant that is indicated for the prophylaxis of organ rejection in adult and pediatric patients receiving allogeneic liver, kidney, heart, or lung transplants, in combination with other immunosuppressant drugs.

The number of annual lung transplants performed increased from 724 in 1999, to 2,248 in 2017. In recent years, over 85.5% of lung transplant recipients are treated with a combination of tacrolimus, mycophenolate mofetil, and steroids.

The FDA granted Orphan Drug designation to Prograf for the prevention of rejection after lung transplant in September 2019.

Solosec® Granules For Trichomoniasis

On July 1, 2021, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced that the FDA has approved their supplemental New Drug Application (sNDA) to ***expand the indication*** of Solosec® (secnidazole) Granules 2Gm, to now include the treatment of trichomoniasis in adults.

This approval makes Solosec the first and only single-dose oral prescription antimicrobial agent approved for the treatment of both trichomoniasis and bacterial vaginosis (BV) in the United States. Solosec was previously approved in 2017 for the treatment of BV in adult women.

Continued on Page 30

Novel Device For Athletes' Brains

Continued from Page 14

professional should be consulted if a user is unsure of whether the Q-Collar is right for them.

For more information, visit: https://q30.com/products-q-collar

The FDA reviewed the device through the De Novo premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type. Along with this authorization, the FDA is establishing special controls for devices of this type, including requirements related to labeling and performance testing. When met, the special controls, along with general controls, provide reasonable assurance of safety and effectiveness for devices of this type. This action creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through FDA's 510(k) premarket process, whereby devices can obtain marketing authorization by demonstrating substantial equivalence to a predicate device.

Note: the Q-Collar does not replace, and should still be worn with other protective sports equipment associated with specific sports activities, such as helmets and shoulder pads. Wearers of the device should not depend on the device to protect them from all harmful effects of head impacts. Users should take steps to avoid direct impact to the head and neck. Data do not demonstrate that the device can prevent concussion or serious head injury. The Q-Collar should not be used if an individual has not been medically cleared to play contact sports.

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New Drugs/Indications

Continued from Page 29

Solosec is a single-dose therapy for oral use. The entire contents of the Solosec packet should be sprinkled onto applesauce, yogurt, or pudding and consumed once within 30 minutes without chewing or crunching the granules (it is *not* intended to be dissolved in any liquid). Note that alcoholic beverages and preparations containing ethanol or propylene glycol should be avoided during treatment with Solosec and for at least 2 days after completing therapy.

Trichomoniasis is the most common non-viral, curable sexually transmitted infection (STI) in the U.S., affecting an estimated 3 to 5 million people every year. It is 4 to 5 times more prevalent in women compared to men. However, 72% of male partners of women with trichomoniasis were also infected, and 77% of those males were asymptomatic. Therefore, it is important for partners to be treated at the same time so that the infection is not passed back and forth. Signs and symptoms in women can include itching, burning, redness or soreness of the genitals, discomfort with urination, and vaginal discharge.

At-risk women with trichomoniasis have an increased risk for pelvic inflammatory disease (PID) and a 2.6 times increased risk for persistent endometritis. Women who are pregnant with inadequately treated trichomoniasis are at an increased risk for pregnancy complications such as pre-term birth, premature rupture of membranes, or chorioamnionitis.

Up to 53% of women with HIV (human immunodeficiency virus) infection also have trichomoniasis. Routine screening of asymptomatic women with HIV infection is recommended because of the adverse events associated with asymptomatic trichomoniasis and HIV infection.

Steven Chavoustie, M.D., FACOG, CCRP, Obstetrician & Gynecologist with the Segal Institute for Clinical Research in Miami, Florida, said: "Trichomoniasis is a highly prevalent STI that can increase an individual's risk for contracting or spreading other STI's, including HIV. For approximately 70% of patients, trichomoniasis infection is asymptomatic. If left untreated, trichomoniasis can persist for months or years and result in adverse reproductive health outcomes, including infertility and preterm birth. For these reasons, screening and treatment for trichomoniasis is crucial. I am pleased there is a new treatment option available to help meet the needs of this patient population."

Bacterial vaginosis is an infection caused by an imbalance of bacteria naturally found in the vagina. It is the most common vaginal infection for women, affecting over 21 million U.S. women each year.

BV provides a high pH, contributing to a favorable environment allowing trichomoniasis to grow. In the Longitudinal Study of Vaginal Flora, women who presented for routine health visits and were diagnosed with BV were 1.5 to 2 times more likely to develop trichomonal, gonococcal, and/or chlamydial infections. Trichomoniasis and BV can increase risks for PID, acquisition of STI's such as gonorrhea, chlamydia, HPV, and herpes simplex virus; and the acquisition or transmission of HIV.

Jon Stelzmiller, President of Specialty for Lupin Pharmaceuticals, commented: "The FDA's approval for the additional indication for Solosec to treat trichomoniasis provides healthcare professionals with an option to treat patients with trichomoniasis and BV, which research demonstrates that approximately 70% of women with trichomoniasis are PCR positive for BV. Additionally, having a treatment option for both trichomoniasis and BV that provides a complete course of therapy in a single dose will help address gaps in care related to adherence, and therefore, may reduce risk factors associated with trichomoniasis or BV, such as PID and other STI's."

Note: female patients who recently had children should be advised to discontinue breastfeeding for 96 hours after administration of Solosec.

Trikafta® - For Kids Ages 6 Through 11 With Cystic Fibrosis & Certain Mutations

On June 9, 2021, Vertex Pharmaceuticals, Inc. of Boston, Massachusetts announced the FDA granted an ***expanded approval*** for Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) Tablets, to now include children with cystic fibrosis ages 6 through 11 years who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator gene, or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data.

Product is ***now available*** in an additional dosage strength of elexacaftor 50mg/tezacaftor 25mg/ivacaftor 37.5mg, and ivacaftor 75mg.

Trikafta was previously approved by the FDA for use in people with cystic fibrosis 12 years and older with at least 1 copy of the F508del mutation or 1 copy of a mutation that is responsive in vitro.

Cystic fibrosis (CF) is a rare, life-shortening genetic disease affecting more than 80,000 people globally. It is a progressive, multisystem disease that affects the lungs, liver, GI tract, sinuses, sweat glands, pancreas, and reproductive tract. CF is caused by a defective and/or missing cystic fibrosis transmembrane conductance regulator (CFTR) protein result-

Continued on Page 32

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66689-109-10	10mg/mL	15mL x 10UD	10263282	5754072	2369569	137984
66689-110-10	10mg/mL	20mL x 10UD	10263018	5754080	2369577	138032

For more information, call VistaPharm at 877-437-8567;
visit www.vistapharm.com or email: info@vistapharm.com

VER21-002

New Drugs/Indications

Continued from Page 30

ing from certain mutations in the CFTR gene. Children must inherit 2 defective CFTR genes (1 from each parent) to have CF themselves.

While there are many different types of CFTR mutations that can cause the disease, the vast majority of all people with CF have at least one F508del mutation. These mutations, which can be determined by a genetic test, or genotyping test, lead to CF by creating non-working and/or too few CFTR proteins at the cell surface. The defective function and/or absence of CFTR protein results in poor flow of salt and water into and out of the cells in a number of organs. In the lungs, this leads to the buildup of abnormally thick, sticky mucus that can cause chronic lung infections and progressive lung damage in many patients that eventually leads to death. The median age of death is in the early 30's.

Terri Laguna, M.D., M.S.C.S., Associate Director of the Cystic Fibrosis Center and Division Head of Pulmonary & Sleep Medicine at the Ann & Robert H. Lurie Children's Hospital of Chicago, said: "Clinical experience with Trikafta in patients 12 and older over the past 20 months has demonstrated this medicine has a meaningful and unprecedented clinical benefit for patients. I look forward to now being able to treat younger patients with this breakthrough medicine, including those who have not presented major signals of disease progression. In addition to bringing Trikafta to a younger patient population, patients not previously eligible for any CFTR modulator will now be able to access a treatment that targets the underlying cause of their disease."

Ultomiris® Injection For Pediatric Paroxysmal Nocturnal Hemoglobinuria

On June 7, 2021, Alexion Pharmaceuticals, Inc. of Boston, Massachusetts announced the FDA has now ***expanded the approval*** of Ultomiris® (ravulizumab-cwvz) Injection for intravenous infusion, to now include children (ages 1 month and older) and adolescents with paroxysmal nocturnal hemoglobinuria.

Product is expected to launch immediately.

Ultomiris is administered intravenously every 8 weeks; or for pediatric patients less than 20kg every 4 weeks, following a loading dose.

Ultomiris, a long-acting C5 inhibitor that offers immediate, complete, and sustained complement inhibition, is now the ***first and only*** FDA-approved medicine for children and adolescents with paroxysmal nocturnal hemoglobinuria.

Paroxysmal nocturnal hemoglobinuria (PNH) is a serious ultra-rare blood disorder with devastating consequences. It is characterized by the destruction of red blood cells, which is also referred to as hemolysis. PNH occurs when the complement system (a part of the body's immune system) over-responds, leading the body to attack its own red blood cells. PNH often goes unrecognized, with delays in diagnosis from 1 to more than 5 years. Patients with PNH may experience a range of symptoms, such as fatigue, difficulty swallowing, shortness of breath, abdominal pain, erectile dysfunction, dark-colored urine, and anemia.

The most devastating consequence of chronic hemolysis is the formation of blood clots, which can occur in blood vessels throughout the body, damage vital organs, and potentially lead to premature death. The prognosis of PNH can be poor in many cases, so a timely and accurate diagnosis, in addition to appropriate treatment, is critical to improving patient outcomes.

Satheesh Chonat, M.D., Pediatric Hematologist & Oncologist at the Aflac Cancer & Blood Disorders Center at Children's Healthcare of Atlanta and Assistant Professor of Pediatrics at the Emory University School of Medicine in Georgia (and principal investigator in the drug's pediatric clinical trial), explained: "It can take months, and sometimes years, to receive a correct diagnosis for PNH, a chronic, progressive, and potentially life-threatening rare disease, which can be an overwhelming experience for children and their families. Managing the disease can be extremely burdensome for these children and their families, who often miss school and work for infusions, blood transfusions, and medical appointments. It's exciting to finally have an approved medicine for these patients who are diagnosed as children."

Since its initial approval in 2018, Ultomiris has quickly become the standard of care in the U.S. for the treatment of adults with PNH. PNH is a complement-mediated disease, which means the symptoms and complications are caused by a lack of regulation, or control, of the complement system, an essential part of the immune system. It is designed to target the part of the complement system at the site of disease activity (terminal complement), while preserving function of other parts of the immune system to be able to fight common pathogens and infections.

Ultomiris reduces both red blood cell destruction in the blood vessels and the risk of thrombosis (blood clot); by providing immediate, complete, and sustained terminal complement inhibition.

Janice Frey-Angel, CEO & Executive Director of the Aplastic Anemia & Myelodysplastic Syndrome International Foundation

Continued on Page 34

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> Single-Dose Vials

NDC #	Strength	Package	ABC	Cardinal	McKesson	Morris Dickson
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16729-526-08	1mg/mL	Pack of 25 Vials	10253231	5694674	1594431	950220

> Multi-Dose Vials (AP-rated to Fresenius' Atropine Sulfate)

16729-512-43	8mg/20mL (0.4mg/ml)	Pack of 10 Vials	10258097	5708219	2314003	045211

> Pre-filled Syringe (AP-rated to Hospira's Atropine Sulfate)

16729-484-45	1mg/10mL	Pack of 10 PFS	10260551	5738844	2346344	104802
16729-484-90	0.5mg/5mL	Pack of 10 PFS	10260550	5738836	2346351	104786
16729-483-03	0.25mg/5mL	Pack of 10 PFS	10260560	5738851	2346328	104794

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Government Agency News

Prevent Type 2 Diabetes–From Home!

On May 11, 2021, the U.S. Centers for Disease Control & Prevention (CDC) announced the release of a prediabetes "risk test," and information within their National Diabetes Prevention Program, in order to help set goals to prevent type 2 diabetes.

Research shows that participating in a structured lifestyle change program can help people with prediabetes prevent or delay type 2 diabetes by 58% (and 71% in those over the age of 60).

To see if you may have prediabetes, take the CDC's one-minute risk test online, at: www.cdc.gov/prediabetes/risktest

In addition, you can make preventing type 2 diabetes easier than ever by joining the CDC-led National Diabetes Prevention Program right from your home. The lifestyle change program is available online via distance-learning or in-person, and includes a video-based series of classes.

The program allows you to learn how to do the following: eat healthy without giving up all the foods you love; add physical activity to your life even if you don't think you have time; deal with stress; cope with challenges that can derail your hard work such as how to choose healthy food when eating out; get back on track if you stray from your plan; and more!

To sign up for the program, visit the following CDC web page: www.cdc.gov/diabetes/prevention/people-at-risk.html

HHS Grant To Expand CURE ID Platform For COVID-19 Treatments

On May 19, 2021, the FDA announced that their Clinical Methodologies Group (ClinMeth) within the Center for Drug Evaluation & Research (CDER) Office of Medical Policy received a $9.2 million grant through the U.S. Department of Health & Human Services (HHS) Office of the Assistant Secretary for Planning & Evaluation's (ASPE) Patient Centered Outcomes Research Trust Fund.

The grant will fund expansion of the CURE ID platform to allow for automated data collection from all of the electronic health records (EHR) worldwide, clinical disease registries for COVID-19, and other difficult-to-treat infectious diseases.

CURE ID is a web-based platform and mobile application that allows the global clinical community to share novel uses of existing drugs for challenging infectious diseases. It was developed by the FDA and NIH's National Center for Advancing Translational Sciences (NCATS).

The Critical Path Institute is now convening a public-private partnership for CURE ID in collaboration with FDA and NCATS. The public-private partnership is known as the CURE Drug Repurposing Collaboratory. For more information, visit: www.fda.gov/drugs/science-and-research-drugs/cure-id-app-lets-clinicians-report-novel-uses-existing-drugs

Over the next 2 years, ClinMeth will work with hundreds of medical institutions to expand CURE ID to include EHR and registry data. As part of the expansion, ClinMeth will work with Johns Hopkins Medicine to develop a tool to automate the extraction of data elements from EHR's and registries into the CURE ID case report form. This infrastructure is being built for COVID-19, but it is also designed for future outbreaks of existing and emerging infectious diseases.

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New Drugs/Indications

Continued from Page 32

in Bethesda, Maryland, stated: "This expanded approval is a significant step forward for the PNH community as we work to elevate awareness of this rare disease in children and adolescents and ensure patients, both pediatric and adult, have meaningful treatment options available. PNH can have significant physical, emotional, and/or psychological impacts on families, and we are pleased there is now an approved medicine for the younger members of our community and the families who care for them."

The FDA granted Ultomiris with Priority Review and Orphan Drug designation for this pediatric PNH indication.

Note: this product is only available through a restricted Risk Evaluation & Mitigation Strategy (REMS) program. Meningococcal infections/sepsis can occur in patients taking Ultomiris, which can become life-threatening or fatal if not recognized and treated early. Patients with unresolved *Neisseria meningitidis* infection or who are not vaccinated against this infection should not take Ultomiris unless the risks of delaying treatment outweigh the risks of developing a meningococcal infection.

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Government Agency News

Continued from Page 34

The data enhancement will enable healthcare providers and researchers interested in patient-centered outcomes research for COVID-19 and other infectious diseases to have access to comprehensive (de-identified) case reports on tens of thousands of patients, including treatment outcomes, such as recovery, deterioration, hospitalization, ICU admission, and death.

By enabling data extraction in an automated fashion, CURE ID may facilitate the clinical, research, and regulatory communities to identify signals of potentially safe and effective COVID-19 therapies. These treatments may be candidates for additional study in randomized clinical trials.

Study Links Sleep Apnea In Children To Increased Risk Of High Blood Pressure In Teen Years

On June 23, 2021, the National Institutes of Health (NIH) announced results of a new study, which found that children with obstructive sleep apnea are nearly 3 times more likely to develop high blood pressure when they become teenagers than children who never experience sleep apnea. However, children whose sleep apnea improves as they grow into adolescence do not show an increased chance of having high blood pressure, which is a major risk factor for heart disease.

The long-term study, one of the largest of its kind in the pediatric population, underscores the seriousness of sleep apnea in children and the importance of early treatment. It was funded by the National Heart, Lung & Blood Institute (NHLBI), a division of NIH.

Obstructive sleep apnea, a common sleep disorder that affects millions worldwide, causes people to briefly and repeatedly stop breathing during sleep. While it occurs mostly in adults, an estimated 10% of school-aged children can also suffer from it. Although almost half of them outgrow the disorder by the time they reach adolescence, another half remain with a chronic and persistent problem. As physicians cannot accurately predict who will outgrow sleep apnea, early treatment may be beneficial to the long-term cardiovascular health of children, the researchers suggest.

While past studies have linked sleep apnea to high blood pressure and an increased risk of heart disease in adults, few have examined the long-term health impact of the disorder in children as they transition to adolescence.

Julio Fernandez-Mendoza, Ph.D., Associate Professor at the Sleep Research & Treatment Center at Penn State College of Medicine in Hershey, Pennsylvania (and lead study author), explained: "Our study showed that pediatric sleep apnea can act as a gateway to future hypertension. Because most cases of sleep apnea go undiagnosed in adults and children alike the problem needs more attention. Sleep apnea and its risk factors should be screened for, monitored, and targeted early in life to prevent future cardiovascular disease."

In the study, researchers enrolled 421 children 5 to 12 years old, and monitored them overnight in a sleep lab. 12% were found to have obstructive sleep apnea, according to pediatric diagnostic criteria. They also measured blood pressure levels in this group.

After 8 years, researchers went back to evaluate the same children again, for both sleep apnea and high blood pressure. At this point, the participants were on average 16 years old (between 12 to 23 years).

The researchers found that children whose sleep apnea continued into adolescence were nearly 3 times more likely to develop high blood pressure compared to those who never had sleep apnea. Those whose sleep apnea began as teenagers and met adult diagnostic criteria were nearly twice as likely to develop high blood pressure than those without sleep apnea. In addition, these teens were also more likely to have a specific form of high blood pressure called orthostatic hypertension, which occurs when standing up rapidly from a prone position and is considered a strong risk factor for heart disease in adulthood.

Obesity is another seemingly driving factor of sleep apnea in the young, researchers said. Growing evidence also suggests that increased inflammation, oxidative stress, and impaired heart function caused by changes in the sympathetic nervous system may be at play, given the independent contribution of sleep apnea to high blood pressure and orthostatic hypertension observed, they added.

Like adult sleep apnea, pediatric sleep apnea can be treated. For some specific cases, surgical removal of the tonsils and adenoids can help. Other cases may require the use of a CPAP machine (continuous positive airway pressure), a device that delivers air through a mask to keep the airway open when worn during sleep. For children with obesity, adopting a healthy eating and exercise plan that leads to weight loss can also help.

Dr. Fernandez-Mendoza encourages parents to talk to their child's pediatrician if they suspect sleep apnea, and to have clinicians to integrate behavioral weight loss in their management of overweight youth with sleep apnea.

Continued on Page 38

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Myxredlin
INSULIN INFUSION

MYXREDLIN

(Insulin Human) in 0.9%
Sodium Chloride Injection
100 units per 100 mL (1 unit/mL)

THE FIRST AND ONLY
READY-TO-USE
INSULIN
INFUSION

Myxredlin (insulin human) in 0.9% Sodium Chloride Injection is now available for purchase through your Baxter representative or wholesaler.

PRODUCT CODE	STRENGTH/VOLUME	NDC#	PACK FACTOR
2G3322	100 units/100 mL	0338-0126-12	12

Myxredlin Insulin Human in 0.9% Sodium Chloride Injection
100 units per 100 mL (1 unit/mL)

IMPORTANT RISK INFORMATION

Indication

Myxredlin is a short-acting human insulin indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.

Contraindications

- During episodes of hypoglycemia
- Hypersensitivity to insulin human or any of the excipients in **Myxredlin**

Warnings and Precautions

- *Hyper- or Hypoglycemia with Changes in Insulin Regimen:* Carry out under close medical supervision and increase frequency of blood glucose monitoring.
- Administer **Myxredlin** intravenously ONLY under medical supervision with close monitoring of blood glucose and potassium levels. Hypokalemia may be life-threatening if not treated.
- Individualize dose based on metabolic needs, blood glucose monitoring results, and glycemic control goal. Dosage adjustments may be needed with changes in nutrition, renal, or hepatic function or during acute illness.
- Adverse reactions observed with insulin human injection include hypoglycemia, allergic reactions, weight gain and edema.
- Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs): Observe for signs and symptoms of heart failure; such as shortness of breath, swelling of your ankles or feet, or sudden weight gain.

Dosage and Administration

- Inspect **Myxredlin** visually before use. It should appear clear and colorless. Do not use **Myxredlin** if particulate matter or coloration is seen.
- Do not add supplementary medication or additives.
- Do not use in series connections.
- Do not shake or freeze. Discard unused portion.

Please see Brief Summary of Prescribing Information for Myxredlin adjacent to this ad.

MAKE **MYXREDLIN** PART OF YOUR RISK REDUCTION STRATEGY

Help reduce insulin compounding errors with **Myxredlin**, the first and only commercially-prepared IV insulin.

ISMP and ASHP guidelines recommend using a commercially-prepared product instead of compounding as a risk reduction strategy for high-alert medications.[1,2]

BRIEF SUMMARY OF PRESCRIBING INFORMATION
See Package Insert for Full Prescribing Information.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Myxredlin safely and effectively. See full prescribing information for Myxredlin.

Myxredlin (insulin human) in sodium chloride injection, for intravenous use.
Initial U.S. Approval: 2019

INDICATIONS AND USAGE
Myxredlin is a short-acting human insulin indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.

DOSAGE AND ADMINISTRATION
– Inspect **Myxredlin** visually before use. It should appear clear and colorless. Do not use **Myxredlin** if particulate matter or coloration is seen.
– Administer **Myxredlin** intravenously ONLY under medical supervision with close monitoring of blood glucose and potassium levels.
– Do not add supplementary medication or additives.
– Do not use in series connections.
– Do not shake or freeze. Discard unused portion.
– Individualize dose based on metabolic needs, blood glucose monitoring results, and glycemic control goal.
– Dosage adjustments may be needed with changes in nutrition, renal, or hepatic function or during acute illness.

DOSAGE FORMS AND STRENGTHS
Injection: 100 units insulin human in 100 mL of 0.9% sodium chloride (1 unit/mL) in a single-dose container

CONTRAINDICATIONS
– During episodes of hypoglycemia
– Hypersensitivity to insulin human or any of the excipients in **Myxredlin**

WARNINGS AND PRECAUTIONS
– *Hyper- or Hypoglycemia with Changes in Insulin Regimen:* Carry out under close medical supervision and increase frequency of blood glucose monitoring.
– *Hypoglycemia:* May be life-threatening. Factors which may increase the risk include changes in nutrition and co-administered medication and patients with renal or hepatic impairment. Increased frequency of blood glucose monitoring is recommended in patients at increased risk.
– *Hypersensitivity Reactions:* Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue **Myxredlin**, monitor, and treat if indicated.
– *Hypokalemia:* May be life-threatening. Monitor potassium levels and treat if indicated.
– *Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs):* Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs.

ADVERSE REACTIONS
Adverse reactions observed with insulin human injection include hypoglycemia, allergic reactions, weight gain and edema.

To report SUSPECTED ADVERSE REACTIONS, contact Baxter Healthcare at 1-866-888-2472 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS
– *Drugs that may increase the risk of hypoglycemia:* antidiabetic agents, ACE inhibitors, angiotensin II receptor blocking agents, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, pentoxifylline, pramlintide, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics.

– *Drugs that may decrease the blood glucose lowering effect:* atypical antipsychotics, corticosteroids, danazol, diuretics, estrogens, glucagon, isoniazid, niacin, oral contraceptives, phenothiazines, progestogens (e.g., in oral contraceptives), protease inhibitors, somatropin, sympathomimetic agents (e.g., albuterol, epinephrine, terbutaline), and thyroid hormones.

– *Drugs that may increase or decrease the blood glucose lowering effect:* Alcohol, beta-blockers, clonidine, lithium salts, and pentamidine.

– *Drugs that may blunt the signs and symptoms of hypoglycemia:* beta-blockers, clonidine, guanethidine, and reserpine.

Please visit www.baxterpi.com for Full Prescribing Information

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Baxter Healthcare Corporation Deerfield, IL 60015 USA

References
1. American Society of Health-System Pharmacists. ASHP guidelines on preventing medication errors in hospitals. Am J Health-Syst Pharm. 2018;75:1493-1517.
2. Institute for Safe Medication Practices (ISMP). ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations; 2016.

USMP/MYX/20-0004(1) 07/20

Government Agency News

Continued from Page 35

The NIH study's researchers are also currently conducting another follow-up study of these youth, now aged 20 to 31 years old, to better understand the long-term impact of childhood sleep apnea on cardiovascular health in adulthood.

New Resources To Help People Quit Smoking

On June 17, 2021, the U.S. Centers for Disease Control & Prevention (CDC) announced that their Office on Smoking & Health (OSH) has released new web content related to medicines that help people quit smoking.

The new content is based on findings from: *Smoking Cessation: A Report of the Surgeon General (Chapter 6);* as well as material on the currently FDA-approved "quit-smoking" medications.

It is the CDC's hope the information will help smokers understand more about the different available medications by explaining the pros, cons, and potential side effects of each. It also has examples of how their past experiences or preferences might suggest specific medicine choices that could help one to quit smoking for good. Critical detailed information on how to use the medicines successfully is included in the web content.

The new pages help people who want to quit smoking, as follows.

1) Select a quit-smoking medicine option (www.cdc.gov/tobacco/campaign/tips/quit-smoking/quit-smoking-medications/which-quit-smoking-medicine-is-right-for-you).
2) Learn how to use the 7 FDA-approved medicines to increase their likelihood of quitting for good (www.cdc.gov/tobacco/campaign/tips/quit-smoking/quit-smoking-medications/how-to-use-quit-smoking-medicines).
3) An additional page focusing on the "7 Common Withdrawal Symptoms" and how they can be managed, is also available (www.cdc.gov/tobacco/campaign/tips/quit-smoking/7-common-withdrawal-symptoms).

Whether or not someone uses a medicine to try to quit smoking, these tips can help increase the likelihood of success. Quitting smoking is one of the most important actions people can take to improve their health. This is true regardless of their age or how long they have been smoking.

More information can be found on the CDC's Learn About Quit-Smoking Medicines web page, at: www.cdc.gov/tobacco/campaign/tips/quit-smoking/quit-smoking-medications

Sharp Declines In Breast & Cervical Cancer Screenings

On June 30, 2021, the U.S. Centers for Disease Control & Prevention (CDC) announced that according to a new research study, the total number of cancer screening tests received by women through the CDC's National Breast & Cervical Cancer Early Detection Program declined by 87% for breast cancer and 84% for cervical cancer during April 2020 as compared with the previous 5-year averages for that month.

Prolonged delays in screening related to the COVID-19 pandemic may lead to delayed diagnoses, poor health consequences, and an increase in cancer disparities among women already experiencing health inequities.

Amy DeGroff, Ph.D., M.P.H., Health Scientist with the CDC (and lead study author), explained: "This study highlights a decline in cancer screening among women of racial and ethnic minority groups with low incomes when their access to medical services decreased at the beginning of the pandemic. They reinforce the need to safely maintain routine healthcare services during the pandemic, especially when the healthcare environment meets COVID-19 safety guidelines."

Screening declines observed in the Early Detection Program coincided with the rapid increase of COVID-19 cases in spring 2020. Factors that might have contributed to the declines during this time include screening site closures and the temporary suspension of breast and cervical cancer screening services due to COVID-19. The requirement or recommendation to stay at home and the fear of contracting COVID-19 also likely deterred individuals from seeking healthcare services, including cancer screening.

The study examined COVID-19's impact on the Early Detection Program's screening services during January to June 2020, which had the following health equity impacts.

- Declines in breast cancer screening varied from 84% among Hispanic women, to 98% in American Indian/Alaskan Native women.
- Declines in cervical cancer screening varied from 82% among Black women to 92% among Asian Pacific Islander women.
- In April, the number of screening tests for breast cancer declined in metro (86%), urban (88%), and rural (89%) areas compared to the respective 5-year averages. The decline for cervical cancer screening tests was 85% and 82% for metro and rural areas, respectively, and 77% for urban areas.
- Screening volumes had begun to recover in all groups by June 2020, the end of the observation period.

Continued on Page 40

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Government Agency News

Continued from Page 38

Dr. DeGroff concluded: "The CDC encourages healthcare professionals to help minimize delays in testing by continuing routine cancer screening for women having symptoms or at high risk for breast or cervical cancer. The Early Detection Program can help women overcome barriers to health equity by educating them about the importance of routine screening, addressing their concerns about COVID-19 transmission, and helping them to safely access screening through interventions like patient navigation."

Rapid Decrease In Lung Cancer & Melanoma Deaths Lead Overall Continued Decline In Cancer Death Rate

On July 8, 2021, the U.S. Centers for Disease Control & Prevention (CDC) announced that according to the latest *Annual Report To The Nation On The Status Of Cancer,* overall cancer death rates continue to decline in both men and women for all racial and ethnic groups in the United States.

During the years 2001 to 2018, declines in lung cancer death rates accelerated; and in more recent years, the death rates for melanoma declined considerably, reflecting a substantial increase in survival for metastatic melanoma.

However, the report also finds that for several other major cancers (including prostate, colorectal, and female breast cancers), the previous declining trends in death rates slowed or disappeared. It also finds that overall cancer incidence rates continue to increase among females, children, and adolescents and young adults. All trends in this report cover the period before the COVID-19 pandemic.

The annual report is a collaborative effort among the American Cancer Society (ACS); the CDC; the National Cancer Institute (NCI) which is part of the National Institutes of Health; and the North American Association of Central Cancer Registries.

The report shows a decrease in death rates for 11 of the 19 most common cancers among men, and for 14 of the 20 most common cancers among women, over the most recent period (2014 through 2018). Although declining trends in death rates accelerated for lung cancer and melanoma over this period, previous declining trends for colorectal and female breast cancer death rates slowed and those for prostate cancer leveled off. Death rates increased for a few cancers, such as: brain, nervous system and pancreas in both sexes, oral cavity and pharynx in males; and liver and uterus in females.

Karen E. Knudsen, M.B.A., Ph.D., American Cancer Society CEO, explained: "The declines in lung cancer and melanoma death rates are the result of progress across the entire cancer continuum, from reduced smoking rates to prevent cancer to discoveries such as targeted drug therapies and immune checkpoint inhibitors. While we celebrate the progress, we must remain committed to research, patient support, and advocacy to make even greater progress to improve the lives of cancer patients and their families."

An analysis of long-term trends in cancer death rates in this year's report also shows that death rate declines accelerated in both males and females from 2001 to 2018. In males, a decline of 1.8% per year in 2001 through 2015 accelerated to a decline of 2.3% per year during 2015 to 2018. In females, a decline of 1.4% per year from 2001 to 2015 accelerated to a decline of 2.1% per year during 2015 to 2018.

The report found that overall cancer death rates decreased in every racial and ethnic group during 2014 through 2018.

However, increases in cancer incidence and death rates or deceleration of previous declining trends for some other cancers such as colorectal and female breast cancers are likely due to risk factors such as obesity.

Norman E. Sharpless, M.D., Director of the NCI, observed: "The continued decline in cancer death rates should be gratifying to the cancer research community, as evidence that scientific advances over several decades are making a real difference in outcomes at the population level. I believe we could achieve even further improvements if we address obesity, which has the potential to overtake tobacco use to become the leading modifiable factor associated with cancer."

The authors report that cancer death rates continued to decrease among children (aged <15 years) and adolescents and young adults (aged 15-39 years), despite an increase in incidence rates from 2001 to 2017. Overall cancer incidence rates in children and adolescents and young adults increased in all racial/ethnic groups except American Indian/Alaska Native (AI/AN) children where rates remained stable. The most common cancer among adolescents and young adults was female breast cancer.

Other key findings include the following.

- Overall cancer incidence rates were higher among men than women in every racial and ethnic group, except Asian/Pacific Islander population, where the rates were similar.
- Overall cancer incidence rates were slightly lower among Black people than Caucasian.
- In contrast, overall cancer death rates were higher among Black people than Caucasian.
- Incidence rates of liver cancer were previously increasing, but data show rates have stabilized among both men and women.

Coronavirus Treatments & News

FDA Authorizes Lower Dose Of REGEN-COV™ Injection For Treatment Of COVID-19

On June 4, 2021, Regeneron Pharmaceuticals, Inc. of Tarrytown, New York announced that the FDA ***updated*** the Emergency Use Authorization (EUA) for REGEN-COV™ Injection for intravenous (IV) use, by lowering the dose to 1,200mg (600mg casirivimab/600mg imdevimab), which is half the dose that was originally authorized (*see November 2020 PPO).*

REGEN-COV is authorized for use to treat mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing >40kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Product remains available for use in all 50 U.S. states. Information on ordering in your area is available online from the National Infusion Center Association (https://covid.infusioncenter.org) as well as HHS, the U.S. Department of Health & Human Services (https://protect-public.hhs.gov/pages/therapeutics-distribution#distribution-locations).

The medication can be administered by IV infusion (as short as 20 minutes) or by 4 subcutaneous (SC) injections, which is an alternative when IV infusion is not feasible and would lead to a delay in treatment. It is now authorized as a co-formulated single vial, or in individual vials to be administered together.

REGEN-COV is a cocktail of 2 monoclonal antibodies, casirivimab and imdevimab, that was designed specifically to block infectivity of SARS-CoV-2, the virus that causes COVID-19, using Regeneron's proprietary VelocImmune® and VelociSuite® technologies. The 2 potent, virus-neutralizing antibodies that form the cocktail bind non-competitively to the critical receptor binding domain of the virus's spike protein, which diminishes the ability of mutant viruses to escape treatment and protects against spike variants that have arisen in the human population.

The updated FDA authorization is based on data from several trials, including a recently presented trial which showed treatment reduced the risk of hospitalization or death by 70% in high-risk non-hospitalized patients, and that the treatment effect was consistent between the 1,200mg and 2,400mg doses.

In addition, in vitro research has shown that REGEN-COV retains potency against the main variants of concern circulating within the U.S., including the P.1 variant (now classified by the World Health Organization as "Gamma") and the B.1.351 variant (now classified by the WHO as "Beta").

In addition, prior to this announcement date (in May 2021), the product's Fact Sheet was updated to expand the definition of eligible patients under the EUA. Patients with certain medical conditions or other factors (for example, race or ethnicity) may be at high risk for progression to severe COVID-19 and are eligible to receive the drug if they become infected.

Recently, the National Institutes of Health COVID-19 Treatment Guidelines Panel also strongly recommended the drug's use in non-hospitalized COVID-19 outpatients at high risk of clinical progression.

The development and manufacturing of REGEN-COV have been funded in part with federal funds from the Biomedical Advanced Research & Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness & Response within the HHS.

Regeneron is collaborating with Roche Group of Basel, Switzerland to increase global supply of this product. Regeneron is responsible for development and distribution of the treatment in the U.S., and Roche is primarily responsible for development and distribution outside the United States.

George D. Yancopoulos, M.D., Ph.D., President & Chief Scientific Officer at Regeneron, said: "Despite increased use of vaccines, thousands of patients are still becoming infected in the U.S. every day, with many at high risk of serious complications from COVID-19. Unfortunately, to date only

Continued on Page 42

Government Agency News

Continued from Page 40

- 2-year relative survival for advanced-stage melanoma cases diagnosed during 2001 through 2009 was stable, but it increased 3.1% per year for those diagnosed during 2009 through 2014.
- 2-year relative survival only slightly increased for early and intermediate-stage melanoma cases diagnosed during 2001 through 2014 (0.03% and 0.4% per year, respectively).

The authors indicate these findings can help inform healthcare providers about the need to increase efforts related to cancer prevention, early detection and treatment, and for the need for equitable implementation of effective interventions, especially among under-resourced populations.

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Coronavirus Treatments & News

Continued from Page 41

a fraction of patients eligible for antibody treatments have received them, which we hope will change based on this updated FDA authorization. Product is readily available and supplied free of charge by the U.S. government. REGEN-COV has also demonstrated potency against the main variants of concern to date in vitro and is the only antibody therapy currently available across the U.S., including in states where variants first identified in Brazil and South Africa are circulating at a higher rate."

Actemra® Injection For Hospitalized COVID-19 Patients

On June 24, 2021, Genentech, Inc. of South San Francisco, California (a member of the Roche Group) announced the FDA has issued an Emergency Use Authorization (EUA) for Actemra® (tocilizumab) Injection for intravenous (IV) infusion, for the treatment of COVID-19 in hospitalized adults and pediatric patients 2 years of age and older who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Actemra is an existing prescription IV infusion medication that has already been FDA-approved for multiple inflammatory diseases, including rheumatoid arthritis.

Actemra is a monoclonal antibody that reduces inflammation by blocking the interleukin-6 receptor. In the case of COVID-19 infection, the immune system can become hyperactive, which may result in worsening of disease. Actemra does not directly target SARS-COV-2.

Levi Garraway, M.D., Ph.D., Chief Medical Officer & Head of Global Product Development for Roche, commented: "Even with the availability of vaccines and declines in deaths from COVID-19 in various parts of the world, we continue to see new hospitalizations from severe forms of the disease. We are pleased that Actemra is now authorized as an option that may help improve outcomes for adults and children hospitalized with COVID-19 in the United States."

In clinical trials of hospitalized patients with COVID-19, Actemra in addition to the routine care patients receive for treatment of COVID-19 (which included corticosteroid therapy), was shown to reduce the risk of death through 28 days of follow-up and decrease the amount of time patients remained hospitalized. The risk of patients being placed on ventilators or death through 28 days of follow-up was also decreased.

The results of 4 randomized, controlled studies for the treatment of COVID-19 in more than 5,500 hospitalized patients suggested that Actemra may improve outcomes in patients receiving corticosteroids and requiring supplemental oxygen or breathing support.

Patrizia Cavazzoni, M.D., Director of the FDA's Center for Drug Evaluation & Research, stated: "This action demonstrates the FDA's commitment to making new therapies available through every stage of the global COVID-19 pandemic. Although vaccines have been successful in decreasing the number of patients who require hospitalization, providing additional therapies for those who do become hospitalized is an important step in combating this pandemic."

Note: this product may cause harm to babies in pregnant women or breastfeeding mothers; patients should discuss their options and specific situation with their doctor. In addition, if a patient is pregnant or becomes pregnant while taking Actemra, they should join the pregnancy registry (call 877-311-8972 or talk to their doctor to enroll).

Olumiant® Now Also For Treatment With Or Without Veklury®, In Hospitalized COVID-19 Patients Requiring Oxygen - Expanded EUA

On July 29, 2021, Eli Lilly & Company of Indianapolis, Indiana and Incyte Corp. of Wilmington, Delaware jointly announced the FDA has ***expanded their approval*** of an Emergency Use Authorization (EUA) for Olumiant® (baricitinib) Tablets 1mg and 2mg, to now also allow for treatment with or without Veklury® (remdesivir) Injection for intravenous use (whereas the EUA was previously restricted to use only in combination with remdesivir).

Continued on Page 44

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Coronavirus Treatments & News

Continued from Page 42

The EUA now provides for the use of Olumiant for treatment of COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation or extracorporeal membrane oxygenation.

Inpatient pharmacies in the U.S. may order Olumiant Tablets 1mg and 2mg, through Lilly's authorized distributors.

Ilya Yuffa, Senior VP & President of Lilly Bio-Medicines, said: "Baricitinib in combination with remdesivir has already provided many people with a treatment option that could help prevent progression to ventilation or death and increase recovery speed for certain hospitalized patients with COVID-19 under its currently authorized use. This FDA action provides physicians with additional treatment regimen options for baricitinib, to continue to meet the urgent medical needs posed by this pandemic. Based on the increasing body of evidence, we are confident in the potential of baricitinib as an important treatment for the hospitalized COVID-19 patient population requiring supplemental oxygen."

Olumiant, a once-daily, oral JAK inhibitor, was discovered by Incyte and licensed to Lilly. It is approved in the U.S. and more than 75 countries as a treatment for adults with moderate to severe rheumatoid arthritis. In December 2009, Lilly and Incyte announced an exclusive worldwide license and collaboration agreement for the development and commercialization of baricitinib and certain follow-on compounds for patients with inflammatory and autoimmune diseases.

REGEN-COV™ For Post-Exposure Prophylaxis In Those At High Risk For Severe COVID-19 Who Are Not Fully Vaccinated - Expanded EUA & New Indication

On July 30, 2021, Regeneron Pharmaceuticals, Inc. of Tarrytown, New York announced that the FDA has ***expanded their approval*** and granted a ***new indication*** of the Emergency Use Authorization (EUA) for the investigational COVID-19 antibody cocktail REGEN-COV™ (casirivimab/imdevimab) Injection, to now also include post-exposure prophylaxis in people at high risk for progression to severe COVID-19 who are not fully vaccinated or are not expected to mount an adequate response to vaccination and have been exposed to a SARS-CoV-2 infected individual; or for those who are at high risk of exposure to an infected individual because of infection occurring in the same institutional setting (such as in nursing homes or prisons).

- For post-exposure prophylaxis use, REGEN-COV 1,200mg (600mg casirivimab and 600mg imdevimab) can be administered by subcutaneous injection (4 injections), or by intravenous infusion (as short as 20 minutes). It is available as a co-formulated single vial, or in individual vials to be administered together.
- For people who aren't expected to mount an adequate immune response to vaccination and who have an ongoing exposure to SARS-CoV-2 for more than 4 weeks, the initial 1,200mg dose can be followed by subsequent repeat dosing of REGEN-COV 600mg once every 4 weeks, for the duration of ongoing exposure.
- In those who require repeat dosing for ongoing exposure, REGEN-COV can also now be administered monthly. This ***new indication*** in people aged 12 and older is in addition to the previously granted authorization to treat non-hospitalized patients.

Experts estimate that approximately 3% of the U.S. population may not respond fully to COVID-19 vaccination because of immunocompromising conditions or immunosuppressive medicines. This includes people receiving chemotherapy, people with hematologic cancers such as chronic lymphocytic leukemia, people receiving stem cells or hemodialysis, people who have received organ transplants, and/or people taking certain medications that might blunt immune response (e.g., mycophenolate, rituximab, azathioprine, anti-CD20 monoclonal antibodies, Bruton tyrosine kinase inhibitors). This authorization enables these groups to use REGEN-COV to prevent infection in post-exposure and certain institutional settings.

Continued on Page 46

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Morris Dickson	108373

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Size: **6** vials

Web Listing

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Coronavirus Treatments & News

Continued from Page 44

REGEN-COV is a cocktail of 2 monoclonal antibodies that was designed specifically to block infectivity of SARS-CoV-2, the virus that causes COVID-19, using Regeneron's proprietary VelocImmune® and VelociSuite® technologies. The two potent, virus-neutralizing antibodies that form the cocktail bind non-competitively to the critical receptor binding domain of the virus's spike protein, which diminishes the ability of mutant viruses to escape treatment and protects against spike variants that have arisen in the human population.

George D. Yancopoulos, M.D., Ph.D., President & Chief Scientific Officer of Regeneron, said: "This FDA authorization enables certain people at high risk of developing severe COVID-19 infection to access REGEN-COV if they have been exposed to the virus; the first time an antibody treatment has been authorized for this purpose. The FDA specifically highlights the needs of immunocompromised people, including those taking immunosuppressive medicines, who may not mount an adequate response to vaccination, who are exposed to a person with COVID-19, or are in an institutional setting and are at high risk of exposure because of infection occurring in the same setting. This decision to expand the use of REGEN-COV in post-exposure settings is a very helpful step, and we continue to work with the FDA as it undertakes its review of REGEN-COV in a broader group of people including in a pre-exposure prophylactic setting for people who are immunocompromised, and in patients hospitalized due to COVID-19."

The development and manufacturing of REGEN-COV have been funded in part with federal funds from the Biomedical Advanced Research & Development Authority (BARDA), part of the U.S. Department of Health & Human Services' Office of the Assistant Secretary for Preparedness & Response.

Regeneron is collaborating with Roche Group of Basel, Switzerland to increase global supply of the antibody cocktail, with Roche primarily responsible for development and distribution outside the United States.

Coronavirus News

Study Shows mRNA Vaccines Reduce Risk Of COVID-19 Infection By 91% For Fully Vaccinated People

On June 7, 2021, the U.S. Centers for Disease Control & Prevention (CDC) announced results from their recent study, which found that mRNA COVID-19 vaccines authorized by the FDA (by Pfizer-BioNTech and Moderna) reduce the risk of infection by 91% for fully vaccinated people. This adds to the growing body of real-world evidence of their effectiveness.

Importantly, this study also is among the first to show that mRNA vaccination benefits people who get COVID-19 despite being fully vaccinated (14 or more days after the second dose); or in those partially vaccinated (14 or more days after the first dose to 13 days after the second dose).

The findings come from 4 weeks of additional data collected in the CDC's surveillance study of healthcare workers, first responders, frontline workers, and other essential workers. These groups are more likely to be exposed to the COVID-19 virus because of their occupations. Preliminary results from this study were first announced a couple of months before this current announcement date *(see March 2021 PPO)*.

In the new analysis, 3,975 participants completed weekly SARS-CoV-2 testing for 17 consecutive weeks (from December 13, 2020 to April 10, 2021) in 8 locations in the United States. Participants self-collected nasal swabs that were laboratory tested for SARS-CoV-2, which is the virus that causes COVID-19. If the tests came back positive, the specimens were further tested to determine the amount of detectable virus in the nose (i.e., viral load) and the number of days that participants tested positive (i.e., viral shedding).

Participants were followed over time and the data were analyzed according to vaccination status. To evaluate vaccine benefits, the study investigators accounted for the circulation of SARS-CoV-2 viruses in the area and how consistently participants used personal protective equipment (PPE) at work and in the community. Once they were fully vaccinated, participants' risk of infection was reduced by 91%. After partial vaccination, the participants' risk of infection was reduced by 81%. These estimates included symptomatic and asymptomatic infections.

To determine whether COVID-19 illness was milder, study participants who became infected with SARS-CoV-2 were combined into a single group and compared to unvaccinated, infected participants. Several findings indicated that those who became infected after being fully or partially vaccinated were more likely to have a milder and shorter illness compared to those who were unvaccinated. For example, fully or partially vaccinated people who developed COVID-19 spent on average 6 fewer total days sick and 2 fewer days sick in bed. They also had about a 60% lower risk of developing symptoms such as

Continued on Page 48

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Heart Health News

Many Adults With Cardiovascular Disease Know The Risks, Yet Still Don't Stop Smoking

On June 9, 2021, the American Heart Association (AHA) of Dallas, Texas announced results of a new research study, which found that many adults with a history of cardiovascular disease continue to smoke cigarettes and/or use other tobacco products, despite knowing it increases their risk of having another cardiovascular event.

To understand how many adults with cardiovascular disease (CVD) continue to use tobacco products, investigators reviewed survey responses from the large, national Population Assessment of Tobacco & Health Study (PATH) to compare tobacco use rates over time. The participants of the current study included 2,615 adults (ages 18 or older) with a self-reported history of heart attack, heart failure, stroke, or other heart disease, who completed 4 surveys over a course of 4 to 5 years.

The first survey occurred from 2013 through 2014, and the last one from 2016 through 2018. When the study began, nearly half of the study participants were women (48.5%); from self-identified responses 77% were white adults, 10.5% were Black adults, 8% were Hispanic adults, and the remainder were multi-racial or other. In 2013 to 2014, nearly one-third of study participants (28.9%) reported using tobacco. This percentage translates to approximately 6 million U.S. adults who use tobacco despite a history of CVD.

Among the tobacco products used by study participants, the following was found.

- Cigarettes were the most common form of tobacco product used (82.8%), followed by any types of cigars (23.7%), and e-cigarettes (23.3%). Many participants used more than 1 type of tobacco product.
- E-cigarette use without concurrent cigarette use among participants with CVD was uncommon (1.1%).
- Use of smokeless tobacco products was reported by 8.2% of participants.
- Use of other tobacco products was uncommon: pipe (3.7%); hookah (3.0%); snus, which is a smokeless tobacco product from Sweden (1.2%); and lastly, dissolvable tobacco (0.3%).

In the final survey 4 to 5 years later, fewer than a quarter of smokers with CVD had quit using tobacco. Participation in a formal smoking cessation program dwindled from 10% of respondents during the second wave of the survey to approximately 2% by the end of the study.

Continued on Page 50

Coronavirus Treatments & News

Continued from Page 46

fever or chills, as compared to those who were unvaccinated. Some study participants that were infected with SARS-CoV-2 did not develop symptoms.

Other study findings suggest that fully or partially vaccinated people who got COVID-19 might be less likely to spread the virus to others. For example, fully or partially vaccinated study participants had 40% less detectable virus in their nose (a lower viral load), and the virus was detected for 6 fewer days (viral shedding) compared to those who were unvaccinated when infected. In addition, people who were partially or fully vaccinated were 66% less likely to test positive for SARS-CoV-2 infection for more than 1 week compared to those who were unvaccinated. While these indicators are not a direct measure of a person's ability to spread the virus, they have been correlated with reduced spread of other viruses, such as varicella and influenza.

Overall, the study findings support the CDC's recommendation to get fully vaccinated against COVID-19 as soon as you can. Everyone 12 years and older is now eligible to get a COVID-19 vaccination in the United States. The CDC has several surveillance networks that will continue to assess how the FDA-authorized COVID-19 vaccines are actually working in real-world conditions in different settings and in different groups of people, such as different age groups and people with different health statuses.

Rochelle P. Walensky, M.D., MPH, Director of the CDC, said: "COVID-19 vaccines are a critical tool in overcoming this pandemic. Findings from the extended timeframe of this study add to the accumulating evidence that mRNA COVID-19 vaccines are effective and should prevent most infections, but that fully vaccinated people who still get COVID-19 are likely to have milder, shorter illness, and appear to be less likely to spread the virus to others. These benefits are another important reason to get vaccinated."

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Heart Health News

Continued from Page 48

Cristian Zamora, M.D., FAHA, Third-Year Internal Medicine Resident at Jacobi Medical Center with the Albert Einstein College of Medicine in Bronx, New York (and study co-lead author), said: "At the conclusion of our study, we were surprised that so few cigarette users with CVD were part of a formal smoking-cessation program. It was also concerning that despite the well-documented benefits of stopping tobacco use after a CVD diagnosis, few people had stopped smoking over the course of the 5-year study."

Additional, notable findings are detailed below.

- Most of the study participants with CVD (95.9%) reported knowing or believing that smoking can cause heart disease in smokers.
- A significant proportion of the study participants (40.2%) said they believed e-cigarettes were less harmful than are combustible cigarettes.
- E-cigarette use varied based upon the general perception of harmfulness of using e-cigarettes, when compared to smoking cigarettes.
- The prevalence of e-cigarette-use and dual-use (smoking both combustible cigarettes and e-cigarettes) was higher among those participants who said they believed e-cigarettes are less harmful than cigarettes, compared to those who believed e-cigarettes are more harmful than cigarettes.
- Dual use of cigarettes and e-cigarettes was more common among study participants than use of e-cigarettes alone.

Rose Marie Robertson, M.D., FAHA, Deputy Chief Science & Medical Officer of the AHA (who was not involved with this study but serves as the Co-Director of the Association's Tobacco Center of Regulatory Science, which provided support for the study), said: "In the United States, heart disease is the leading cause of death, resulting in more than 365,000 deaths in 2018. A major risk factor for CVD, including heart events and stroke, is smoking. Fortunately, research clearly shows that quitting smoking can help prevent heart disease, even among people who have had it in the past. The findings of this new study are disturbing, although perhaps not surprising. These results indicate that critical public policies and interventions are needed to address this preventable, leading cause of death and disability not just in the U.S., but around the world."

Trends for tobacco use varied by gender, age, race/ethnicity, and other socioeconomic characteristics of study participants. Below are the findings.

- Among adults with CVD, use of any tobacco product was associated with younger age.
- Men were more likely than women to use any tobacco product except for e-cigarettes.
- Women were 70% more likely than men to use e-cigarettes.
- Hispanic participants were 60% less likely than white participants and 50% less likely than Black participants to use any tobacco product.
- Lower levels of household income were associated with a higher likelihood of using any tobacco product.
- Participants living below the poverty line (annual income of $23,550 in 2013 and $25,100 in 2018 for a family or household of 4 living in one of the 48 contiguous states or the District of Columbia) were twice as likely to report using any tobacco product compared to those living at twice the poverty level or above.
- There were no significant differences in the use of any tobacco product among adults with CVD across regions in the United States.

Dr. Zamora concluded: "Our findings support the need for stronger commitment from a multidisciplinary team, including primary care professionals, social workers, psychologists, and cardiologists, to provide smoking cessation therapies and counseling to people with CVD. Healthcare reforms and public health policies should improve the availability of tobacco-cessation programs and tools for high-risk populations."

Some Blood Pressure-Lowering Meds Linked To Less Memory Decline In Older Adults

On June 21, 2021, the American Heart Association (AHA) of Dallas, Texas announced the results of a new research study, which found that older adults taking blood pressure-lowering medications known to cross the blood-brain barrier had better memory recall over time compared to those taking other types of medicines to treat high blood pressure.

High blood pressure, or hypertension, is a risk factor for cognitive decline and dementia in older adults. Nearly half of American adults have elevated blood pressure. Treating high blood pressure with blood pressure-lowering medicines reduced the cases of mild cognitive impairment by 19% in one large clinical trial.

Angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), calcium channel blockers, and diuretics are different classes of blood pressure-lowering medicines. Each class acts in a different way to reduce blood pressure, and some cross the blood-brain barrier, thereby impacting cognitive function.

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Heart Health News

Continued from Page 50

Daniel A. Nation, Ph.D., Associate Professor of Psychological Science in the Institute for Memory Impairments & Neurological Disorders at the University of California in Irvine (and study author), explained: "Research has been mixed on which medicines have the most benefit to cognition. Studies of ARBs and ACE inhibitors have suggested these medicines may confer the greatest benefit to long-term cognition, while other studies have shown the benefits of calcium channel blockers and diuretics on reducing dementia risk."

This is the first meta-analysis to compare the potential impact over time of blood pressure lowering medicines that do cross the blood-brain barrier versus those that do not. The medicines were evaluated for their effects on several cognitive domains, including attention, language, verbal memory, learning, and recall.

Dr. Nation added: "Hypertension occurs decades prior to the onset of dementia symptoms, affecting blood flow not only in the body but also to the brain. Treating hypertension is likely to have long-term beneficial effects on brain health and cognitive function later."

For the meta-analysis, researchers gathered information from 14 studies of nearly 12,900 adults ages 50 years and older, which included studies done in the United States, Australia, Canada, Germany, Ireland, and Japan. Results included the following:

- Older adults taking blood pressure-lowering medicines that cross the blood-brain barrier had better memory recall for up to 3 years of follow-up compared to those taking medicines that do not cross the blood-brain barrier even though they had a higher level of vascular risk;
- Adults taking hypertension medications that did not cross the blood-brain barrier had better attention for up to 3 years of follow-up.

Jean K. Ho, Ph.D., Postdoctoral Fellow at the University of California in Irvine (and study co-author), said: "These findings represent the most powerful evidence to-date linking brain-penetrant ACE-inhibitors and angiotensin receptor blockers to better memory. It suggests that people who are being treated for hypertension may be protected from cognitive decline if they medications that cross the blood-brain barrier."

Blood pressure is considered elevated at 120/80mm Hg and higher. The current AHA/American College of Cardiology guidelines for treating high blood pressure suggest changes to diet and activity levels to lower blood pressure and adding blood pressure-lowering medication for people with levels of 130/80mm Hg or higher depending on their risk status. If blood pressure reaches 140/90mm Hg, then blood pressure-lowering medication is recommended.

Limitations of this analysis are that the authors could not account for differences in racial/ethnic background based on the available studies, and there is a higher proportion of men versus women in the group who took medications that cross the blood-brain barrier. This is an important area of future research since previous studies have shown that people from various racial/ethnic backgrounds may respond differently to different blood pressure medications.

People With High-Deductible Health Plans Less Likely To Seek ER Treatment For Chest Pain

On June 29, 2021, the American Heart Association (AHA) of Dallas, Texas announced results of a new research study, which found that people who must spend $1,000 or more annually in out-of-pocket medical deductibles under their healthcare insurance plan were less likely to seek care in the emergency room for chest pain and less likely to be admitted to the hospital during these visits, compared to people who have health insurance plans with an annual deductible of $500 or less.

Each year, up to 7 million people are cared for in an emergency room (ER) for chest pain.

Chest pain can occur when the heart muscle doesn't get enough oxygen-rich blood. It may feel like pressure or squeezing in the chest. The discomfort also can occur in the shoulders, arms, neck, jaw, or back and may also feel like indigestion. Chest pain may be a symptom of an underlying heart problem, usually coronary heart disease (CHD). There are many types of chest pain, and all chest pain should be checked by a healthcare professional.

Health insurers and employers who administer their own health plans are increasingly shifting the cost burden of healthcare to patients, researchers noted. By 2020, more than half of U.S. employees were enrolled in a high-deductible health plan, according to the national Employer Health Benefits Survey. Previous research has shown that insurance status and financial concerns affect patients' decisions to delay or skip seeking care for many medical conditions.

Shih-Chuan Chou, M.D., M.P.H., S.M., Emergency Care Physician in the Department of Emergency Medicine at Brigham & Women's Hospital in Boston, Massachusetts (and lead study author), explained: "Shifting the high cost of healthcare from insurers and employers to patients has become a trend across the United States. Our study is one of the first to examine the impact of

Continued on Page 52

Heart Health News

Continued from Page 51

a high-deductible healthcare plan on people's decisions to go to an ER for chest pain."

Using the claims database from a nationwide U.S. health insurer, researchers identified patients ages 19 to 63, enrolled between 2003 and 2014, whose employers offered only low-deductible health plans ($500 or less/year) in the first year, and then mandated enrollment in a high-deductible health plan ($1,000 or more/year) during the second year. The control group included members who were enrolled in a low-deductible health plan for 2 straight years.

The study included more than a half-million employees in the high-deductible group and nearly 6 million employees in the control group. In both groups, the average age was 42; about half of the participants were women, and about two-thirds were non-Hispanic white adults.

Researchers matched people in both groups according to patient-specific demographic and clinical characteristics and employer characteristics (such as the total number of employees) to ensure similarity. They examined whether switching to a high-deductible health plan changed employees' use of the ER for chest pain during the first year (the low-deductible year) compared to the second year (the high-deductible year). They also compared changes in annual patient outcomes from year 1 to year 2 between the high-deductible health plan group and the matched control group (those with low-deductible plan for 2 consecutive years).

Researchers found the following.

- Switching to a high-deductible health plan was associated with a 4% reduction in ER visits for chest pain.
- Enrollment in a high-deductible health plan was associated with an 11% decrease in ER visits for chest pain leading to hospitalization.
- Among low-income patients, those who had high-deductible health plans were nearly one-third more likely to have a heart attack during a subsequent hospitalization 30 days after their initial ER visit for chest pain.

Dr. Chou added: "People with higher deductibles delay treatment and are sicker when they show up in the ER for chest pain. When people with low-incomes are switched to high deductible plans, they are disproportionately impacted financially and so is their health. These findings underscore the consequences associated with the affordability of health insurance and health expenses, especially for patients with chest pain, one of the most common reasons for ER visits. Cost is a real factor for patient outcomes. Clinicians need to consider actively including cost in our discussions with patients and in shared decision-making. Insurers and employers need to consider how they will manage high-deductible plans going forward, particularly given the health impact on their employees."

Imaging Test May Predict Those Most At Risk Of Heart Complications From COVID

On July 8, 2021, Johns Hopkins Medicine of Baltimore, Maryland announced results of a new research study that shows a type of echocardiogram (a common test to evaluate whether a person's heart is pumping properly), may be useful in predicting which patients with COVID-19 are most at risk of developing atrial fibrillation (an irregular heartbeat that can increase a person's risk for heart failure and stroke, among other heart issues).

The new findings also suggest that patients with COVID-19 who go on to develop atrial fibrillation more commonly have elevated levels of heart-related proteins called troponin and NT-proBNP in blood test samples.

Allison Hays, M.D., Medical Director of Echocardiography Programs at Johns Hopkins Hospital (and senior study author), noted: "If further studies confirm the findings, this could lead to new therapies to prevent strokes and heart attacks in certain COVID-19 patients who are at the highest risk."

Previous studies of complications and long-term effects of SARS-CoV-2 infection have found that patients who are hospitalized with COVID-19 have more than double the rate of arrhythmias, including atrial fibrillation and atrial flutter, a similar rapid rhythm that can lead to heart failure and stroke. But exactly how the virus causes these heart complications, and who is most at risk of developing atrial fibrillation because of COVID-19, has been poorly understood.

In this study, Dr. Hays and her colleagues compared 80 patients with COVID-19 with 34 patients who did not have COVID-19 who were also treated at the Johns Hopkins Hospital in the intensive or intermediate care units for respiratory issues. None of the patients had a history of heart arrhythmia. In the study, carried out between March and June 2020, the researchers analyzed echocardiograms of hospitalized patients, applying a special kind of analysis that is called "speckle-tracking strain," in order to determine how well the left atrium of the heart moves with each heartbeat.

The team found that, overall, patients with COVID-19 had reduced function of their left

Continued on Page 54

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Despite initial satisfactory response to i.v. dantrolene there have been reports of fatality, which involve patients who could not be weaned from dantrolene after initial treatment. The administration of i.v. dantrolene is associated with loss of grip strength and weakness in the legs, as well as drowsiness and dizziness. There have been reports of thrombophlebitis following administration of intravenous dantrolene. Tissue necrosis secondary to extravasation has been reported. Injection site reactions (pain, erythema, swelling), commonly due to extravasation, have been reported. Fatal and non-fatal liver disorders of an idiosyncratic or hypersensitivity type may occur with dantrolene sodium therapy.

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Heart Health News

Continued from Page 52

atrium, the chamber of the heart that receives oxygenated blood from the lungs. Left atrial strain a measure of the movement of the left atrium's walls, was significantly lower in patients with COVID-19 (28.2% compared with 32.6%); and left atrial emptying fraction, a measure of how much blood the atrium empties with each contraction was also lower in the patients with COVID-19 (55.7% as compared with 64.1%).

Moreover, left atrial strain was even lower among the 30% of patients with COVID-19 who developed atrial fibrillation or flutter during their hospital stay compared with other patients with COVID-19 (22.3% compared to 30.4%). This suggests that speckle-tracking analysis, and specifically, left atrial strain measurement, could be used to predict which patients with COVID-19 are at highest risk of arrhythmias and develop preventive treatments.

Erin Goerlich, M.D., Cardiology Fellow at the Johns Hopkins University School of Medicine (and first author of the paper), said: "A lot of patients already get echocardiograms while in the hospital; the addition of strain analysis requires no extra scanning of the patient. So, this is a safe and affordable new data point that can clue us in about who might develop atrial fibrillation." Echocardiograms cost on average about $2,000 and are generally covered by health insurance.

When the researchers looked at the blood of patients with COVID-19 who developed atrial fibrillation, they saw some differences compared with other patients with COVID-19. People who developed atrial fibrillation had higher levels of troponin (0.07 versus 0.03) and NT-proBNP (946 versus 231), two known markers of heart stress.

Dr. Goerlich suggested: "This tells us that COVID-19 patients with high levels of these biomarkers should be followed more closely, and may benefit from an echocardiogram test."

Dr. Hays cautioned that the current study didn't test whether treating patients with COVID-19 with blood thinners could help prevent the complications that can result from atrial fibrillation, which has been suggested by some clinicians. Blood thinners are generally prescribed to atrial fibrillation patients to lower the risk of blood clots and strokes. Dr. Hays concluded: "However, the new study suggests that treating certain people, those with especially low left atrial strain, for instance, could be one path forward. More research is needed in this area. We're also actively studying how these effects on the heart might persist after SARS-CoV-2 infection. It's important to know whether those measures of strain and emptying fraction improve over time."

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Coronavirus Tests

First COVID-19 IgG Antibody Test Receives EUA

On July 9, 2021, Ortho Clinical Diagnostics, Inc. of Raritan, New Jersey announced the FDA has approved VITROS® Anti-SARS-CoV-2 IgG Quantitative Test, which is the first quantitative type COVID-19 IgG antibody test to receive the FDA's Emergency Use Authorization (EUA).

This new quantitative COVID-19 IgG antibody test targets the S1 spike protein and is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2. The test offers ***100%*** specificity and excellent sensitivity.

The new test is calibrated to the World Health Organization (WHO) International Standard for anti-SARS-CoV-2 IgG antibodies, which gives clinicians and public health leaders a standard tool to measure antibody response to SARS-CoV-2. This uniform data is a first step toward understanding the rise and fall of antibodies in individuals and the long-term impacts of the COVID-19 pandemic on communities and the overall population.

Ortho's VITROS COVID-19 Testing Solutions help labs meet the demands of the pandemic with reliable, high-throughput testing solutions that offer SARS-CoV-2 infection and antibody testing on Ortho's VITROS Systems. Up to 150 antibody tests or up to 130 antigen tests can be processed each hour, which are already installed in more than 1,000 labs across all 50 states in the United States.

The VITROS SARS-CoV-2 Antigen Test is a high-throughput, highly accurate test that detects acute infection of SARS-CoV-2. It includes IgG and Total tests that target the S1 spike protein, and a Total test that targets the nucleocapsid protein.

The VITROS COVID-19 Performance Dashboard allows labs to easily view COVID-19 antibody testing data and enables more informed decisions. The web-based system provides productivity information regarding ortho analyzers, test volumes, workload balance, HIT levels, and reagent efficiency.

First Direct-To-Consumer Saliva COVID-19 PCR Test For Children Ages 5+ & Adults

On July 7, 2021, PRNewswire.com reported that Wren Laboratories LLC of Concord, Connecticut announced the FDA has granted an Emergency Use Authorization (EUA) for the Wren PCR Saliva Test, the nation's first direct-to-consumer saliva PCR COVID-19 test for children ages 5 and over.

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Coronavirus Tests

Continued from Page 54

Wren has been offering one of the nation's most accurate saliva tests since October 2020. Now, in response to the growing need for easy, accurate tests that detect all known variants, this new EUA authorization offers the convenience and accuracy of saliva PCR testing to help facilitate back-to-school and work conveniently, safely, and cost-effectively.

Wren's over-the-counter saliva polymerase chain reaction (PCR) test is now available for bulk and online purchase by schools, businesses, event organizers, and individuals. It can be shipped directly to offices, schools, and homes across the U.S., without the need for a medical prescription.

Mark Kidd, Ph.D., Laboratory Director for Wren, said: "We have heard from a number of schools that having a widely available saliva PCR test for children as young as 5 years-old is a game-changer. This ease of saliva PCR testing coupled with high accuracy and ability to detect all currently known variants in asymptomatic and symptomatic people is a key component to instilling peace of mind and getting back to schools and workplaces and other everyday events."

The Wren PCR test is simple to use, has little room for error, requires just a teaspoon of saliva and does not need any invasive nasal swabbing or similar unpleasant collection approaches. Saliva samples are collected in 2 to 3 minutes, and Wren delivers digital results to the users and schools and workplaces within 24 hours of receipt of the sample.

With some of the nation's most accurate results, Wren's PCR test has proven to detect viral loads of <2,500NDU/mL, the most sensitive saliva-based assay on the market. Over-the-counter antigen testing is significantly less accurate than traditional PCR approaches and are typically hundreds of times less sensitive than PCR assays. The U.S. Centers for Disease Control & Prevention (CDC) specifically recommends PCR to confirm infection with the virus.

Organizations reviewing their testing protocols should consider the following.

- **Regular testing builds confidence.** Testing provides peace of mind to help Americans get back to the office, school, and other life events. With the most accurate results available, and effectiveness in detecting all known variants, Wren's PCR test provides the peace of mind that is needed now to get back to work and school.
- **Easy access and long shelf life.** Wren's saliva collection kits are available for online purchase for consumers and are shelf stable for more than one year making them ideal for schools, businesses, and anyone who needs a regular testing program.
- **Clear digital results.** In many settings, people need to show proof of negative tests before returning to work, school, travel, or other large gatherings. Wren's TAPS (Testing & Passporting Solution) provides testers with a secure mobile app to track their testing status and receive updates on their smartphones. Employers, educational institutions, and sports authorities can also use the system to track testing information on employees, students, and members, initiate testing requests, and receive results rapidly.

Several education and community organizations have relied on Wren's PCR Saliva COVID tests throughout the past year, including Independence Northwest of Naugatuck, Connecticut and Children's Center of Hamden, Connecticut.

Selma N. Ward, CEO of The Children's Center of Hamden, remarked: "Access to accurate and easy to use tests provides faster peace of mind, is in line with our safety protocols, and has also reduced absenteeism. The Center uses Wren's PCR Saliva Test as part of its protocol with staff who have been in close contact with infected people. Access to accurate and easy to use tests provides faster peace of mind, is in line with our safety protocols, and has also reduced absenteeism."

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Flu Vaccine Products & News

Increased Availability Of Fluzone® High-Dose Quadrivalent Influenza Vaccine With Newly Licensed Manufacturing Facility

On June 17, 2021, Sanofi Pasteur, Inc. of Swiftwater, Pennsylvania announced they were granted approval by the FDA's Center for Biologics Evaluation & Research for an additional influenza manufacturing facility, also located in Swiftwater.

The newly completed facility further expands production and distribution of their Fluzone® High-Dose Quadrivalent vaccine for the upcoming 2021-2022 influenza season in the United States and will create up to 200 additional manufacturing jobs.

Fluzone High-Dose Quadrivalent is a vaccine indicated for adults 65 years of age and older for the prevention of influenza disease caused by influenza A and B strains contained in the vaccine.

This product is the only vaccine approved by the FDA for superior flu protection in adults 65 years of age and older, compared to a standard-dose flu vaccine. With 4-strain protection, it builds on the legacy of the trivalent formulation, which was clinically proven to be 24.2% more effective at preventing flu than standard-dose Fluzone (influenza vaccine) in adults 65 or older.

In addition, Fluzone High-Dose has demonstrated protection against influenza and its related complications including cardiorespiratory events, pneumonia, and hospitalization.

Elaine O'Hara, Head of North America Commercial Operations for Sanofi Pasteur, explained: "We are experiencing fast-growing demand for our vaccine in the U.S. and globally, given the 10 years of data demonstrating protection from flu and its related complications. Our new facility will complement our existing capacities to produce enough high-dose vaccine for all people 65 and older in as many countries as possible this flu season and beyond, supporting the needs of healthcare providers and patients."

Vaxneuvance™ Vaccine For Prevention Of Invasive Pneumococcal Disease

On July 16, 2021, Merck & Co., Inc. of Kenilworth, New Jersey announced the FDA approval of Vaxneuvance™ (pneumococcal 15-valent conjugate) Vaccine, indicated for active immunization for the prevention of invasive disease caused by 15 *Streptococcus pneumoniae* serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F), in adults 18 years of age and older.

Pneumococcal disease is an infection caused by bacteria called *Streptococcus pneumoniae,* or *pneumococcus*. Different strains of this bacteria are called serotypes. Invasive pneumococcal disease (IPD) occurs when the bacteria enters and infects a sterile site such as blood, cerebrospinal fluid (CSF), pleural fluid, joint fluid or pericardial fluid. Non-invasive disease includes otitis media, sinusitis, and bronchitis. Approximately 80% of all adult IPD burden is among adults 50 years of age and older.

Serotypes 3, 22F, and 33F contribute significantly to the burden of IPD; and serotype 3 is the leading cause of IPD in adults in the United States.

Jose Cardona, M.D., Indago Research & Health Center, Inc. of Hialeah, Florida (and coordinating investigator for the drug's study trial), said: "Some adults, including older adults or those with certain chronic medical conditions or immunocompromising conditions, are at increased risk for pneumococcal disease and its serious, sometimes life-threatening complications. The FDA's approval of Vaxneuvance is based on robust Phase 2 and 3 studies assessing immune responses in a broad range of adult populations, and provides an important new option in protection from invasive pneumococcal disease."

The FDA granted Vaxneuvance with Priority Review and Breakthrough Therapy designations.

Shingrix Vaccine Now Also For Shingles In Immunocompromised Adults 18 Years & Older - Expanded Indication

On July 26, 2021, GlaxoSmithKline (GSK) of Philadelphia, Pennsylvania announced that the FDA has approved an ***expanded indication*** of Shingrix Vaccine (zoster vaccine recombinant, adjuvanted), now also for the prevention of herpes zoster (shingles) in adults aged 18 years and older who are or who will be at increased risk of shingles due to immunodeficiency or immunosuppression caused by known disease or therapy.

Continued on Page 58

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News Briefs

Viiv Healthcare & Halozyme Agreement For ENHANZE® Drug Delivery Technology In HIV

On June 22, 2021, Halozyme Therapeutics, Inc. of San Diego, California and ViiV Healthcare of Research Triangle, North Carolina jointly announced a global collaboration and license agreement that gives Viiv exclusive access to Halozyme's ENHANZE® drug delivery technology, a recombinant human hyaluronidase PH20 enzyme (rHuPH20) for specific targets used in the treatment and prevention of HIV (human immunodeficiency virus).

ENHANZE drug delivery technology provides ViiV Healthcare with more opportunities to develop ultra-long acting medicines (dosing intervals of 3 months or longer), with its long-acting portfolio and pipeline products. Plans are shortly underway to initiate the first experiments with the technology for the investigational, long-acting cabotegravir to be used in the prevention of HIV, which is currently administered every 2 months.

The PH20 enzyme breaks down a substance called hyaluronan (HA) that is found in the body's subcutaneous space (under the skin) that acts as a barrier to the flow of fluid. By breaking down HA locally at the injection site and temporarily removing that barrier, large amounts of fluid can be injected into the subcutaneous space and dispersed. This facilitates the rapid delivery of large volume fluids by subcutaneous injection, potentially reducing the treatment burden of injectable drugs and providing optimized

Continued on Page 60

Flu Vaccine Products & News

Continued from Page 56

Originally FDA-approved in 2017 for the prevention of shingles in adults 50 years of age or older, the approval for this new population expands the number of people who can be protected against shingles.

A non-live, recombinant sub-unit adjuvanted vaccine, Shingrix is given intramuscularly in two doses, 2 to 6 months apart. However, for adults who are or will be immunodeficient or immunosuppressed due to known disease or therapy and who would benefit from a shorter vaccination schedule, the second dose can be administered 1 to 2 months after the first dose.

Shingrix is the first shingles vaccine indicated for use in those who are at increased risk of the disease due to being immunodeficient or immunosuppressed due to disease or therapy. It combines a non-live antigen, to trigger a targeted immune response, with a specifically designed adjuvant system to generate a varicella zoster virus-specific immune response that can help overcome the decline in immunity as people age.

Immunocompromised individuals are at greater risk of shingles and associated complications than immunocompetent individuals. According to a recently published report from Avalere Health and supported by GSK, more than 17 million doses of recommended vaccines, including Shingrix, were missed by adults during 2020, in part due to the COVID-19 pandemic.

There are an estimated 1 million cases of shingles in the United States each year. More than 99% of those over 50 years old are infected with varicella zoster virus (VZV), and 1 in 3 Americans will develop shingles in their lifetime. The risk increases to 1 in 2 for adults aged 85 years and older. Shingles is caused by the reactivation of VZV, the same virus that causes chickenpox. Nearly all older adults have the VZV dormant in their nervous system, waiting to reactivate with advancing age. As people age, the cells in the immune system lose the ability to maintain a strong and effective response to VZV reactivation.

Shingles typically presents as a painful, itchy rash that develops on one side of the body and can last for 3 to 4 weeks. The pain associated with shingles is often described as burning, shooting or stabbing. Even once the rash is gone, a person can experience postherpetic neuralgia (PHN), being pain that lasts from at least 3 months up to several years. PHN is the most common complication of shingles, occurring in 10% to 18% of all shingles cases.

Thomas Breuer, M.D., M.Sc., Chief Medical Officer of GSK Vaccines, said: "We're proud to offer Shingrix in the U.S. for the prevention of shingles in those who are immunocompromised, with the FDA granting a broad indication for use in adults at increased risk of this disease. Older age and being immunocompromised are the most common risk factors for shingles disease. GSK is committed to this important patient population at increased risk for shingles disease and its complications by bringing them a vaccine option that can help prevent this painful condition. In addition to this new patient population, there are more than 100 million adults 50 years and older in the U.S. already recommended to receive Shingrix. We know many of these individuals missed recommended vaccines during the pandemic and we hope this can be a reminder to them to catch up on all their immunizations, including Shingrix."

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News Briefs

Continued from Page 58

treatment options to patients. The HA is restored under the skin via normal processes within 24 to 48 hours.

The license gives ViiV exclusive use of Halozyme's proprietary rHuPH20 technology for 4 specific HIV medicine targets: integrase inhibitors, reverse transcriptase inhibitors limited to nucleoside reverse transcriptase inhibitors (NRTI) and nucleoside reverse transcriptase translocation inhibitors (NRTTI's), capsid inhibitors, and broadly neutralizing monoclonal antibodies that bind to the gp120 CD4 binding site.

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "Many people living with HIV and those vulnerable to HIV tell us that for a variety of reasons, taking medicine every day is a challenge, and we have listened to them. We believe long-acting medicines are the future of HIV therapies and will help address these unmet needs. Our collaboration with Halozyme will keep us at the forefront of developing additional, innovative new options for HIV treatment and prevention as we work towards reducing the burden of HIV treatment."

ViiV Healthcare is a global company specializing in HIV treatments, that is majority owned by GlaxoSmithKline plc, with Pfizer Inc. and Shionogi Ltd. as shareholders.

Lilly Acquires Protomer Technologies

On July 14, 2021, Eli Lilly & Company of Indianapolis, Indiana announced the acquisition of Protomer Technologies Inc. of Pasadena, California, a private biotech company.

Protomer's proprietary peptide and protein-engineering platform is used to identify and synthesize molecules that can sense glucose or other endogenous modulators of protein activity.

Founded in 2015 and based in Pasadena, California, Protomer is engineering next-generation protein therapeutics that can sense molecular activators in the body. The company's proprietary chemical biology-based platform enables the development of therapeutic peptides and proteins with tunable activity that can be controlled using small molecules. Protomer has used this approach toward advancing a portfolio of therapeutic candidates, including glucose-responsive insulins that can sense sugar levels in the blood and automatically activate as needed throughout the day.

Ruth Gimeno, Eli Lilly VP of Diabetes Research & Clinical Investigation, stated: "Lilly has long strived to make life better for people living with diabetes and we have a continued determination to provide real solutions, including innovation in insulin therapy. Glucose-sensing insulin is the next frontier and has the potential to revolutionize the treatment and quality of life of people with diabetes by dramatically improving both therapeutic efficacy and safety of insulin therapy. Protomer's glucose-sensing insulin program, based on its proprietary molecular engineering of protein sensors (MEPS) platform, is showing significant promise and Lilly is excited to enhance our diabetes pipeline with the company's innovative technology."

BioDelivery Sciences To Acquire Rights To Elyxyb™ For Acute Migraine

On August 4, 2021, BioDelivery Sciences International, Inc. of Raleigh, North Carolina and Dr. Reddy's Laboratories, Inc. of Princeton, New Jersey jointly announced they have entered into an agreement in which BioDelivery will acquire the U.S. and Canadian rights to Elyxyb™ (celecoxib) Oral Solution 25mg/mL, which is the only FDA-approved ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults.

The product's launch is currently planned for the first quarter of 2022.

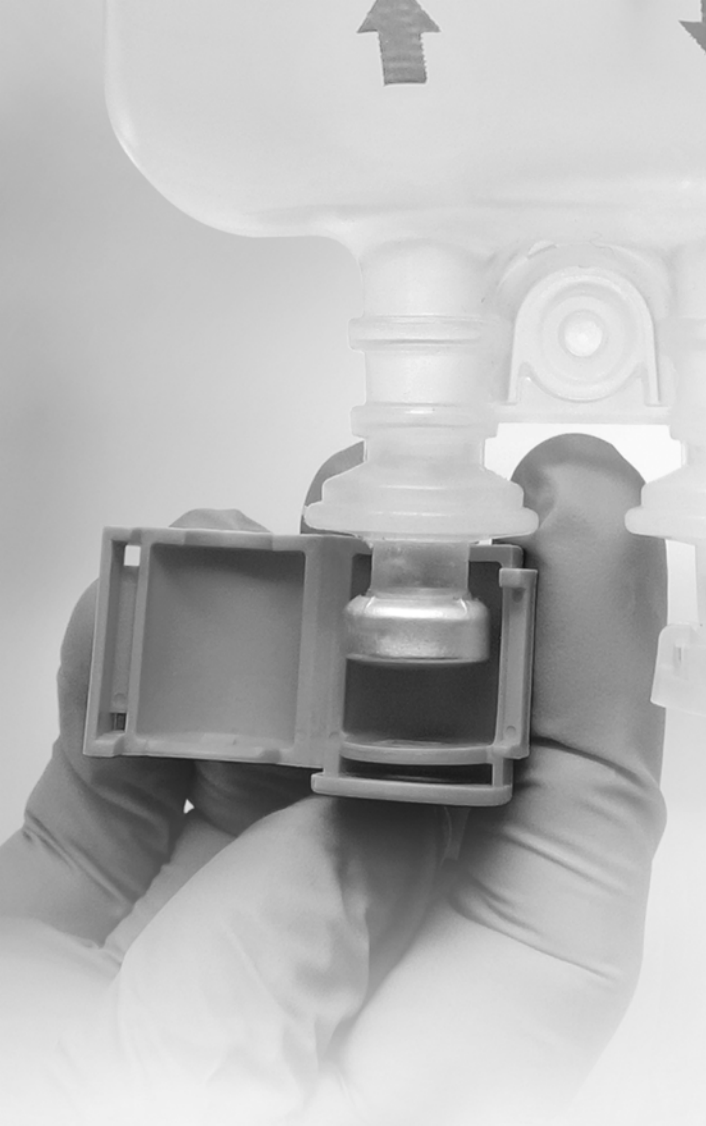
Elyxyb is an oral solution of celecoxib, formulated using a self-micro emulsifying drug delivery system that improves solubility and bioavailability of the drug leading to better absorption. This allows for the administration of a lower dose of drug to achieve therapeutic effect relative to a conventional oral solid dosage form.

In the drug's clinical studies, it demonstrated a rapid onset of action, which is critically important to patients suffering from acute migraine attacks. Elyxyb's unit-dose oral solution makes it convenient for patients to take it immediately upon emergence of acute migraine attacks.

Thomas Smith, M.D., Chief Medical Officer at BioDelivery, commented: "We are excited to acquire Elyxyb. The clinical data are quite compelling, including a meaningful speed of onset with Tmax achieved in approximately 60 minutes. Additionally, in the two pivotal studies conducted, the percentage of patients achieving a "Most Bothersome Symptom" freedom at 2 hours post-dose was significantly greater among patients receiving Elyxyb, compared to those receiving placebo. In Study 2, the percentage of patients achieving headache pain freedom 2 hours post-dose was significantly greater among patients receiving Elyxyb, compared to those receiving placebo. We believe that this profile, coupled with the ready-to-use oral solution, make Elyxyb an attractive option for the acute treatment of migraine in adults."

The closing of the transaction is subject to the satisfactory completion of customary closing conditions, including the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

Continued on Page 62



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News Briefs

Continued from Page 60

BioDelivery will also be conducting a pediatric study for the medication, which has the potential to address the significant unmet need for migraine treatments in children and young adolescents.

Note: patients should be informed about the symptoms of serious cardiovascular (CV) events and the steps to take if they occur. To minimize the potential risk for an adverse CV event in NSAID-treated patients, use Elyxyb for the fewest number of days per month as needed, based on individual treatment goals. Avoid the use of Elyxyb in patients with a recent myocardial infarction (MI) unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events.

Bayer Acquires Vividion Therapeutics

On August 4, 2021, Bayer Corporation in Whippany, New Jersey announced the acquisition of Vividion Therapeutics, Inc. of San Diego, California, a biopharmaceutical company utilizing novel discovery technologies to unlock high value, traditionally undruggable targets with precision therapeutics.

Vividion's platform is able to produce a variety of small molecule therapies across indications, with initial focus on targets relevant to oncology and immunology. Their lead programs include multiple precision oncology targets and precision immunology targets, with ongoing efforts on a transcription factor NRF2 antagonist for the potential treatment of NRF2 mutant cancers, as well as NRF2 activators for various inflammatory diseases such as irritable bowel disease, among other pre-clinical programs.

Following closing of the acquisition, Bayer will own full rights to Vividion's proprietary discovery platform, which comprises three integrated, synergistic components: a novel chemoproteomic screening technology, an integrated data portal, and a proprietary chemistry library. The acquisition of Vividion strengthens Bayer's small molecule capabilities, and expands Bayer's reach into new modalities.

Identification of drug candidates for proteins that are considered undruggable is a great challenge in drug discovery. Vividion's chemoproteomic screening platform is able to identify previously unknown binding pockets on well-validated protein targets by screening chemical probes against the entire human proteome to assess selectivity. This yields highly potent and selective compounds that provide a wide therapeutic window for a variety of areas of high-unmet medical need. Vividion's technology has already proven its applicability pre-clinically in oncology and immune-related diseases, and has the potential to expand into additional indications.

Jeff Hatfield, CEO at Vividion, said: "Despite advances in genomics, structural biology and high-throughput screening, about 90% of disease-causing proteins cannot be targeted by current therapies due to the lack of a known addressable binding site. Our proprietary chemoproteomic platform technology addresses the key limitations of conventional screening techniques and allows us to discover previously unknown, or cryptic, functional pockets on the surface of proteins and identify small molecules that selectively bind to those targets. When combined with Bayer's expertise in the development of small molecules to market and patient, an unparalleled position comes into existence to unlock undruggable targets and generate first-in-class novel compounds for the benefit of patients."

To preserve its entrepreneurial culture as an essential pillar for nurturing successful innovation, Vividion will continue to operate as an independent organization on an arm's length basis, remaining accountable to advance its technology and portfolio while benefiting from the experience and infrastructure of Bayer as a global pharmaceutical company.

Closing of the transaction is contingent on the customary closing conditions, including receipt of the required regulatory approvals, and is expected to take place by the end of 2021.

Sanofi To Acquire Translate Bio

On August 3, 2021, Sanofi U.S. of Bridgewater, New Jersey announced that as part of Sanofi's endeavor to accelerate the application of messenger RNA (mRNA) to develop therapeutics and vaccines, the company has entered into a definitive agreement with Translate Bio, a clinical-stage mRNA therapeutics company, under which Sanofi will acquire all outstanding shares of Translate Bio. Both company's Boards of Directors have unanimously approved the transaction.

Following the successful completion of the tender offer, a wholly owned subsidiary of Sanofi will merge with Translate Bio.

In June 2018, Sanofi and Translate Bio entered into a collaboration and license agreement to develop mRNA vaccines, which was further expanded in 2020 to broadly address current and future infectious diseases. There are two ongoing mRNA vaccine clinical trials under the collaboration: a COVID-19 vaccine study and a mRNA seasonal influenza (flu) vaccine trial study.

On the therapeutic side, Translate Bio has an early-stage pipeline in cystic fibrosis and other

Continued on Page 65

Innovative Health News

High Frequency Spinal Cord Stimulation Therapy For Chronic Painful Diabetic Neuropathy

On July 19, 2021, Nevro Corp. of Redwood City, California announced that the FDA approved its Senza® System, specific to Nevro's unique 10kHz stimulation. It is indicated for the treatment of chronic pain associated with painful diabetic neuropathy.

Nevro now has the ***only*** spinal cord stimulation system approved by the FDA for this specific indication, and is now available.

Diabetic neuropathy may affect as many as 50% of people with diabetes, and is a type of nerve damage. High blood sugar caused by diabetes can injure nerves throughout the body, but most often damages nerves in the legs and feet. Depending on the affected nerves, its symptoms can range from pain and numbness in the legs and feet to problems with the digestive system, urinary tract, blood vessels and heart. For some it can be mild, but for others, it can be quite painful and disabling, thus becoming painful diabetic neuropathy (PDN).

Frances Broyles, Medical Director of Diabetes/Endocrinology & Nutrition at Swedish Health Services in Seattle, Washington, said: "Diabetic neuropathy is one of the most prevalent and debilitating, chronic complication of diabetes, and for years, PDN patients have struggled with a lack of effective treatment options when conventional medications fail or are not tolerated. The ability to now offer Nevro's proven 10kHz Therapy, which may enable discontinuation of long-term drug therapy and eliminate unwanted drug side effects, is a welcome addition as a treatment option for my PDN patients dealing with this challenging condition. My personal practice experience with the Nevro 10kHz Therapy was nothing short of life changing for the patient."

Amplatzer™ Amulet™ Device FDA-Approved For Atrial Fibrillation Patients At Risk Of Stroke

On August 16, 2021, Abbott Laboratories of Abbot Park, Illinois announced that the FDA approved the company's Amplatzer™ Amulet™ Left Atrial Appendage Occluder to treat people with atrial fibrillation who are at risk of ischemic stroke. The device offers immediate closure of the left atrial appendage: an area where blood clots can form in people suffering from atrial fibrillation, thus reducing their risk of stroke and immediately eliminating the need for blood-thinning medication.

The left atrial appendage (LAA) is a small pouch connected to the upper left chamber of the heart. For people with atrial fibrillation (AFib), the most common of the persistent arrhythmias, or irregular heartbeats, the heart's ability to effectively pump blood can be disrupted, allowing blood to pool and collect in the LAA causing an increased risk for clotting. If clots reach the blood stream, they can travel to the brain and cause a stroke. For patients with AFib who are unable to take blood-thinning medication long term, physicians may opt for occlusion (or closure) of the LAA through a minimally invasive procedure using devices like the Amulet to seal off the LAA entirely and reduce the risk of stroke.

Before this approval, the only minimally invasive option for LAA occlusion for U.S. physicians and their patients was a solution with a single component to seal the LAA that requires blood-thinning drugs to heal and additional patient monitoring to ensure closure. In contrast, Abbott's Amulet uses dual-seal technology to completely and immediately seal the LAA. Amulet recipients do not need to use blood-thinning medication following the procedure. Additionally, the device can treat a broad range of anatomies and has the widest range of occluder sizes on the market; it is also recapturable and repositionable to ensure optimal placement.

Dhanunjaya Lakkireddy, M.D., Physician for the Kansas City Heart Rhythm Institute at HCA Midwest Health in Overland Park, Kansas (and principal investigator for the drug's trial study), said: "As the world's population continues to age, we're seeing a surge in atrial fibrillation cases, and with that comes increased risk of stroke. The approval of Abbott's Amulet device provides physicians with a treatment option that reduces the risk of stroke and eliminates the need for blood-thinning medication immediately after the procedure, which is incredibly valuable given the bleeding risks associated with these medicines."

Researchers Tell Doctors To Avoid Routine Urinary Tests For Older Delirium Patients

On July 28, 2021, Johns Hopkins Medicine of Baltimore, Maryland announced results of a new high value healthcare study that led their researchers to conclude and recommend physicians avoid routine, and unnecessary, urine testing of older patients with delirium when there are no clinical signs or symptoms of infection.

Milad Memari, M.D., Senior Resident in Internal Medicine at the Johns Hopkins University School of Medicine (and lead study author), said: "Just because it's an easy test to obtain doesn't mean it's an appropriate test. Our research indicates that patients, who are elderly, delirious, and unable to give their medical history, may be more likely to suffer from the consequences of unnecessary testing and treatment. Urine tests are often one of the first that doctors call for in these situations."

Continued on Page 66

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2021 NPPA Conference, August 17-19 - Bally's Las Vegas

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News Briefs

Continued from Page 62

rare pulmonary diseases. In addition, discovery work is ongoing in diseases that affect the liver, and Translate Bio's mRNA therapeutic platform may be applied to various classes of treatments, such as therapeutic antibodies or vaccines in areas such as oncology.

Sanofi's recent acquisition of Tidal Therapeutics expanded the company's mRNA research capabilities in both immuno-oncology and inflammatory diseases. The Translate Bio acquisition further accelerates Sanofi's efforts to develop transformative medicines using mRNA technology.

Paul Hudson, Sanofi CEO, said: "Translate Bio adds an mRNA technology platform and strong capabilities to our research, further advancing our ability to explore the promise of this technology to develop both best-in-class vaccines and therapeutics. A fully owned platform allows us to develop additional opportunities in the fast-evolving mRNA space. We will also be able to accelerate our existing partnered programs already under development. Our goal is to unlock the potential of mRNA in other strategic areas such as immunology, oncology, and rare diseases in addition to vaccines."

The consummation of the tender offer is subject to customary closing conditions, including the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other usual conditions.

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Exhibiting & Sponsoring Vendors, 2021 NPPA

Continued from Page 64

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In addition, find 63 Bronze Exhibitors
On the NPPA Website: www.PharmacyPurchasing.com

♦♦♦♦♦♦♦♦

Legal News

Movantik® Patent Litigation Settlement

On July 22, RedHill Biopharma Inc. of Raleigh, North Carolina, AstraZeneca Pharmaceuticals of Wilmington Delaware, and Nektar Therapeutics of San Francisco, California announced they have jointly entered into a settlement and license agreement with Apotex, Inc. and Apotex Corp., resolving their patent litigation in response to Apotex's Abbreviated New Drug Application (ANDA) seeking FDA approval to market a generic version of RedHill's Movantik® (naloxegol) Tablets.

RedHill acquired the rights to Movantik from AstraZeneca in April 2020, excluding Europe and Canada.

Under the terms of the settlement agreement, Apotex may not sell a generic version of Movantik in the U.S. until October 1, 2030 (subject to FDA approval), or earlier under certain circumstances.

The parties to the settlement agreement have also agreed to file a stipulation and order of dismissal with the U.S. District Court of Delaware, which will conclude this litigation with respect to Apotex. As required by law, the parties will submit the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The settlement with Apotex does not end RedHill's ongoing litigation against the other one ANDA filer.

EpiPen® Direct Purchaser Case Dismissed

On July 27, 2021, Viatris Inc. of Pittsburgh, Pennsylvania announced that the U.S. District Court of Kansas granted a motion to Mylan Pharmaceuticals, Inc. (now a Viatris Inc. company) to dismiss in a lawsuit brought against it and Pfizer, Inc. by KPH Healthcare Services Inc., on behalf of an asserted class of direct purchasers related to EpiPen® (epinephrine) Injectable products.

The Court agreed with the company's argument that KPH lacked the legal standing to assert the claims in its lawsuit, and dismissed the case in its entirety with an option for KPH to file a limited amended complaint within 30 days.

The court agreed with the company's argument that KPH lacked the legal standing to assert the claims in its lawsuit, and dismissed the case in its entirety with an option for KPH to file a limited amended complaint within 30 days.

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Innovative Health News

Continued from Page 63

In their research, Memari and his colleagues reviewed previous studies by others that evaluated the practice of conducting urine tests in hospitals, specifically those for older people with delirium. From one of these studies, Memari's team learned that 83% of nearly 3,000 patients in hospitals across the nation including patients ages 65 and older, were given antibiotic therapy based on urine cultures positive for bacteria, even though the microbes may in fact be harmless.

Another investigation showed that 27% (92 out of 343 patients) received antibiotics when they did not have clinical signs of urinary tract infections, and they had suffered from harmful long-term consequences of these treatments that may have been unnecessary.

Dr. Memari added: "If elderly, delirious patients are reporting symptoms, including pain or burning with urination, increased frequency of urination and pain in the lower abdomen, or exhibit clinical signs including fevers, low blood pressure, elevated heart rate or an elevated white blood cell count, urine testing may be appropriate. If they don't have symptoms or clinical signs consistent with infection, then their doctors should forego urinary testing to avoid complications from unnecessary antibiotic treatment, and as a result, longer hospitalizations, slower recovery times and poorer outcomes. A large number of older patients grow bacteria in urine cultures but may not actually have urinary infections. The focus should be avoiding unnecessary testing to prevent treatment of bacteria that are a normal, healthy part of a patient's urinary ecosystem. Also, the more a patient is treated for a urinary infection, the more likely that person will develop a resistance to antibiotics. This makes urinary infections harder to treat in future instances, and has contributed to the public health issue of increased antibiotic resistance in a highly vulnerable population. When treating older populations, we have to remember the principle of 'first, do no harm.' Our team hopes this review of existing research will get a conversation started in hospitals across the country about curbing unnecessary urine testing to avoid causing long-term harm to, and provide more precise and individualized care for, elderly patients with delirium."

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List Of Off-Patent Drugs

Continued from Page 1

Action Plan (DCAP) web page online, as follow: www.fda.gov/drugs/guidance-compliance-regulatory-information/fda-drug-competition-action-plan

As previously announced, in support of DCAP and the U.S. Pharmacopeia (USP) Generics Access Plan (www.usp.org/our-impact/generics), USP has prioritized the development of monographs associated with drug products on the OPOE list.

They have successfully developed 12 monographs (associated with 11 drug products on the OPOE list). 9 of these monographs are currently official in the USP-NF, and 3 will be official on December 1, 2021. USP is continuing these efforts to help support the development of new generic drug products to foster a more competitive marketplace for medicines.

As of December 2021, the FDA will publish 2 versions of the list: one for prescription drug products, and one for over-the-counter (OTC) drug products that are approved and marketed under an NDA (new drug).

Those 2 lists will each be separated into 3 sections, as follows.

1) Part I identifies those drug products for which FDA could immediately accept an ANDA without prior discussion.
2) Part II identifies drug products for which ANDA development or approval may raise potential legal, regulatory, or scientific issues that should be addressed with the Agency prior to considering submission of an ANDA.
3) The Appendix identifies NDA drug products that were removed from Part I or Part II of the list because one or more ANDAs referencing such NDA drug products have been approved since the previous list publication.

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Thanks To Renewing NPPA Members

Full Pharmacy Members

Sherry Larose, Pharmacy Purchasing & Lead Technician, SEARHC Mt. Edgecumbe Hospital, Sitka, AK

Regena Millis, Pharmacy Purchasing Agent, Cullman Regional Medical Center, Cullman, AL

Dr. Jared Hatchard, Community Pharmacy Operations Manager, Sun Life Family Health Center, Casa Grande, AZ

Brian Fleury, Corporate Pharmacy Purchasing Analyst, Comprehensive Pharmacy Services (CPS), Tucson, AZ

Christian Miranda, Pharmacy Buyer, Providence Infusion & Pharmacy Services, Anaheim, CA

Daryl Malabute, Pharmacy Buyer, Antelope Valley Hospital, Lancaster, CA

Elaine Montijo, Pharmacy Buyer, Sharp Chula Vista Medical Center, National City, CA

Ed Arinduque, Pharmacy Buyer, Sharp Mary Birch Hospital, San Diego, CA

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Marianne Marchant, Pharmacy Buyer, Shepherd Center, Atlanta, GA

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Kathy Stocker, Pharmacy Buyer, Robert Wood Johnson (RWJ) University Hospital, Hamilton, NJ

Antonette Armijo, Pharmacy Purchasing Tech/Buyer, University of New Mexico Hospital, Albuquerque, NM

Joanie MacIntosh, Corporate 340B Analyst, Comprehensive Pharmacy Services (CPS), Las Vegas, NV

Carl Whittemore, Pharmacy Purchasing Manager, Faxton St. Luke's Healthcare, Utica, NY

Leon Jacobs, Pharmacy Program Manager-Procurement, Baylor Scott & White Health, Dallas, TX

Moriah Willbur, Pharmacy Program Manager, Baylor University Medical Center, Dallas, TX

Robin Halverson, Pharmacy Inventory Technician, Gundersen Lutheran Medical Center, La Crosse, WI

Jennifer Hoff, Pharmacy Purchasing Specialist, Gundersen Lutheran Medical Center, La Crosse, WI

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Continued on Page 68

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*). 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 website's "Member Incentives Program" page for details.

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Angela Nerusciac, Pharmacy Specialty Tech, Moffitt Cancer Center, Tampa, FL

Jawad Vohra, Senior Pharmacy Procurement Specialist, King Faisal Hospital (Royspec), Hanover, MD

Heather Erickson, Corporate Analyst-340B Solutions, Comprehensive Pharmacy Solutions (CPS), Brooklyn Park, MN

Chaunda Ehlers-Smith, Warehouse Supervisor & Pharmacy Buyer, Emerging Health Infusion Pharmacy, Tigard, OR

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Leslie Linderman, Pharmacy Buyer, Baylor University Medical Center, Dallas, TX

Adam Ortiz, Methodist Specialty Pharmacy, Methodist Specialty & Transplant Hospital, San Antonio, TX

Amanda Lamm, Pharmacy Buyer, Skagit Valley Hospital, Mt. Vernon, WA

Associate Pharmacy Members

Natasha Chinell, Pharmacy Buyer/Pharmacy Tech, Skagit Valley Hospital, Mt. Vernon, WA

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Renewing NPPA Members

Continued from Page 67

Associate Pharmacy Members

Christina Lopez, Pharmacy Resource Supervisor, Sun Life Family Health Center, Casa Grande, AZ

Ken LeBoutillier, Pharmacy Services Manager, Sarasota Memorial Hospital, Sarasota, FL

Staci Roth, Pharmacy Operations Support Specialist, St. Cloud Hospital, St. Cloud, MN

Executive (GPO) Members

Delorice Robb, Division Pharmacy Analyst, HealthTrust Supply Chain-East FL Division, Miramar, FL

Jeremy Plummer, Manager of Pharmacy Systems, HealthTrust Purchasing Group, Nashville, TN

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Editorial

Continued from Page 4

Discarding medications properly at home is important for another reason–to keep our pets safe. By simply tossing drugs in the trash, it is an easy access point for our furry friends to root around and ingest something that could make them very sick or kill them.

So, when patients walk into our pharmacy and ask where they can dispose of their loved one's medications, we no longer need to turn them away since we now have these safe options available to help them avoid that unnecessary anxiety.

Whether it's one bottle or multiple bags with various forms of medicines needing to be disposed of, we have a way to ease our frustration levels as well as respect the environment.

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NPPA Website Resources

NPPA Members: here below is all of the information about the resources you can find 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" section: 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.

Pharmacy Buyers Forum on the NPPA Website: please note that we have now ***removed*** access to our old Pharmacy Buyers Forum web page, which was an online "chat" forum established in order to allow for networking with your fellow Pharmacy Buyers across the country. It was removed after determining that over the space of the past year or more, it was just not being used as often as it used to be, and especially so more recently. However, see the below.

Facebook *"Pharmacy Buyers"* group: one of our NPPA members and Annual Conference attendees **Cassidy Russell,** setup a new Facebook *"Pharmacy Buyers"* group page in the winter of 2019, which has approximately 200 Buyers in the Facebook group and is growing steadily. You should have more luck with responses to your various questions and networking attempts there now, once you request to join the group and get approved. To join, go to your Facebook account and search on "Pharmacy Buyers", or go directly to the page, here: www.facebook.com/groups/334035183936954

NPPA sincerely hopes these resources help you to be a better Pharmacy Buyer!

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E-Blast & NPPA Website Banner Advertising - 2022

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 allowed.

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) - 2022

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
Inside Back Cover	$625.00
Center Spread (2 pages)	$600.00 (x 2)
Editorial-Adjacent	$575.00

Note: Premium Ad Positions are reserved & paid in advance, please inquire first.

Standard Positions (full page, right facing)	**Gross Rate**
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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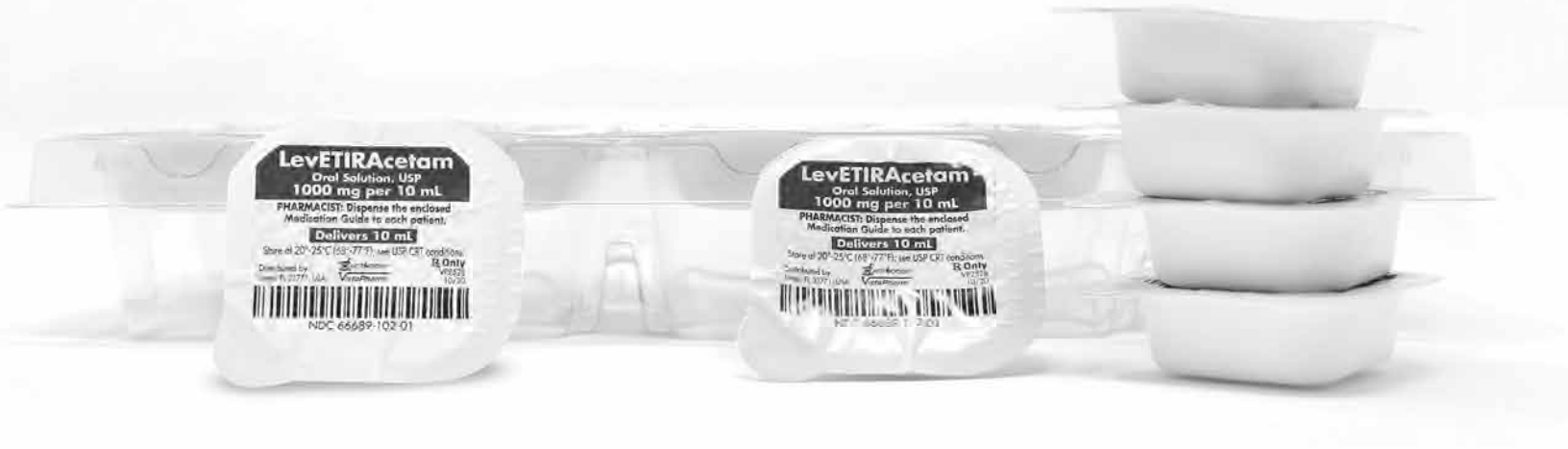
For Questions or to send completed Order Forms for any of the above Advertising options,
Send email to: Advertising@PharmacyPurchasing.com

VistaPharm®



LEVETIRACETAM ORAL SOLUTION, USP

500 mg/5 mL & 1000mg/10 mL

- EXACT DOSING FOR THIS CRITICAL SEIZURE DRUG
- EASILY SCANNABLE BARCODE
- GRAPE-FLAVORED PRODUCT IN MULTIPLE SIZES UNIT-DOSE CUPS

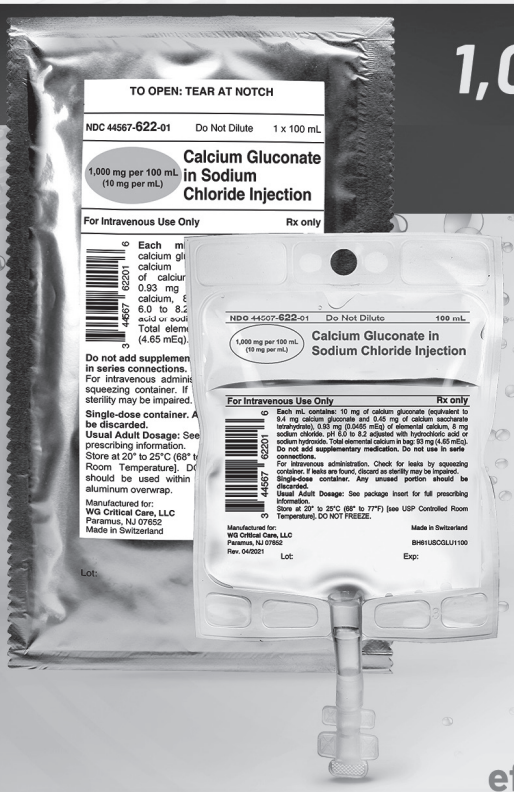
XACTDOSE™

VistaPharm NDC	Case Pack	Description	Amerisource Bergen	Cardinal	McKesson	Morris & Dickson
66689-028-50	50	500 mg/5 mL	078-497	4276887	1478361	028506
66689-0102-20	50	1000mg/10mL	10254733	5705777	2304962	042127

For more information, call VistaPharm at 877-437-8567,
visit www.vistapharm.com or email: info@vistapharm.com

Now Available! Another Choice

Calcium Gluconate
in Sodium Chloride Injection



1,000 mg per 100 mL (10 mg per mL)

FDA APPROVED READY TO USE BAG

- **SHELF STABLE** at controlled room temperature storage[1]
- **FITS IN AUTOMATED DISPENSING CABINETS**
- **60 DAYS STABILITY OUTSIDE OF THE OVERWRAP**

ALSO AVAILABLE

2,000 mg per 100 mL (20 mg per mL)

1,000 mg per 50 mL (20 mg per mL)

Enhanced patient safety, efficient workflow & convenience

CONVENIENT ORDERING THROUGH YOUR WHOLESALER!

NDC # 44567	Bar Code	Total Amount	Fill Volume	Container Type	Concentration	Pack Size	Shelf Life	WHOLESALER ITEM NUMBERS			
								Amerisource Bergen	Cardinal	McKesson	Morris & Dickson
622 - 24		1,000 mg	100 mL	100 mL Premix Bag	10 mg/mL	24	24 months	10260989	5740469	2349777	106666
620 - 24		1,000 mg	50 mL	100 mL Premix Bag	20 mg/mL	24	36 months	10209105	5503305	3672185	511089
621 - 24		2,000 mg	100 mL	100 mL Premix Bag	20 mg/mL	24	36 months	10225251	5547013	3959640	718312

Indications and Usage
Calcium Gluconate in Sodium Chloride Injection is a form of calcium indicated for pediatric and adult patients for the treatment of acute symptomatic hypocalcemia.
Limitations of Use: The safety of Calcium Gluconate in Sodium Chloride Injection for long term use has not been established.

Important Safety Information
Contraindicated in hypercalcemia and in neonates receiving ceftriaxone. Warnings and Precautions: cardiac arrhythmias may occur with concomitant cardiac glycoside use; use caution when administering with ceftriaxone as a precipitate may form in the IV line; tissue necrosis and calcinosis may occur with or without extravasation; hypotension, bradycardia and cardiac arrhythmias may occur with rapid administration; contains aluminum which may cause toxicity. The most common adverse events are local soft tissue inflammation and necrosis; calcinosis cutis and calcification related to extravasation; vasodilation, decreased blood pressure, bradycardia, cardiac arrhythmia, syncope and cardiac arrest.

Please see full Presribing Information, inluding Warnings, Precautions, and Important Safety Information for this product at the WGCC website.

References: 1. On file WG Critical Care, LLC. To request data on file, please contact Customer Service at 1-888-493-0861 or CustomerService@wgccrx.com

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U.S. Patent Number 10, 130, 646

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