PHARMNOTES

February 2023

Date: 3/10/2023

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Drug Safety Alert Notification

- No drug safety alert published in February.

New FDA-Approved Drug Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
JESDUVROQ™ (DAPRODUSTAT) TABLETS	GLAXOSMITHKLINE	2/1/2023

THERAPEUTIC CLASS
Blood Products and Modifiers

FDA-APPROVED INDICATION(S)
Jesduvroq™ is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months.
Limitations of Use:
- Not shown to improve quality of life, fatigue, or patient well-being.

Not indicated for use:
- As a substitute for transfusion in patients requiring immediate correction of anemia.
- In patients not on dialysis.

DOSAGE AND ADMINISTRATION
- Administer orally once daily, with or without food.
- Pre-treatment and on-treatment evaluations of anemia, iron stores, and liver tests.
- Individualize dosing and use the lowest dose of Jesduvroq™ sufficient to reduce the need for red blood cell transfusions. Do not target a hemoglobin higher than 11 g/dL.

DOSAGE FORMS AND STRENGTHS
Tablets: 1mg, 2mg, 4mg, 6mg and 8mg

SAFETY PROFILE

CONTRAINDICATIONS
- Strong cytochrome P450 2C8 (CYP2C8) inhibitors such as gemfibrozil
- Uncontrolled hypertension

WARNINGS AND PRECAUTIONS
- **BLACK BOX WARNING**: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, AND THROMBOSIS OF VASCULAR ACCESS
  - Jesduvroq™ increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE).
  - Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels.
  - No trial has identified a hemoglobin target level, dose of Jesduvroq™, or dosing strategy that does not increase these risks.
  - Use the lowest dose of Jesduvroq™ sufficient to reduce the need for red blood cell transfusions.
- Risk of Hospitalization for Heart Failure: Increased in patients with a history of heart failure.
- Hypertension: Worsening hypertension, including hypertensive crisis may occur. Monitor blood pressure. Adjust anti-hypertensive therapy as needed.
- Gastrointestinal Erosion: Gastric or esophageal erosions and gastrointestinal bleeding have been reported.
- Not indicated for treatment of anemia of CKD in patients who are not dialysis-dependent.

WARNINGS AND PRECAUTIONS (CONT.)
- Malignancy: May have unfavorable effects on cancer growth. Not recommended if active malignancy

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥10%) are hypertension, thrombotic vascular events, and abdominal pain.

DRUG INTERACTIONS
- Moderate CYP2C8 Inhibitors: Reduce starting dose.
- CYP2C8 Inducers: Monitor hemoglobin and adjust the dose of Jesduvroq™ as appropriate.

USE IN SPECIFIC POPULATIONS
- Pregnancy: May cause fetal harm.
- Lactation: Breastfeeding not recommended until one week after the final dose.
- Hepatic impairment: Reduce the starting dose in patients with moderate hepatic impairment. Jesduvroq™ is not recommended in severe hepatic impairment.

Orphan status: No

DRUG NAME	MANUFACTURER	APPROVAL DATE
LAMZEDE™ (VELMANASE ALFA-TYCV) INJECTION	CHIESI FARMACEUTICI S.P.A.	2/16/2023

THERAPEUTIC CLASS

Genetic, Enzyme, or Protein Disorder: Replacement, Modifiers, Treatment

FDA-APPROVED INDICATION(S)

Lamzede™ is a recombinant human lysosomal alpha-mannosidase indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.

DOSAGE AND ADMINISTRATION

- For females of reproductive potential, verify that the patient is not pregnant prior to initiating treatment.
- Consider pretreating with antihistamines, antipyretics, and/or corticosteroids prior to Lamzede™ administration.
- Recommended Lamzede™ dosage is 1 mg/kg (actual body weight) administered once every week as an intravenous infusion.

DOSAGE FORMS AND STRENGTHS

For injection: 10 mg of velmanase alfa-tycv as a lyophilized powder in a single-dose vial for reconstitution.

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS

- None.

WARNINGS AND PRECAUTIONS

- **BLABK BOX WARNING**: SEVERE HYPERSENSITIVITY REACTIONS
  - Hypersensitivity Reactions Including Anaphylaxis: Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available. If a severe hypersensitivity reaction occurs, discontinue Lamzede™ immediately and initiate appropriate medical treatment.
- Infusion-Associated Reactions (IARs): If severe IARs occur, discontinue Lamzede™ and initiate appropriate medical treatment.
- Embryo-Fetal Toxicity: May cause fetal harm. Advise females of reproductive potential to use effective contraception during treatment and for 14 days after the last dose if Lamzede™ is discontinued.

ADVERSE REACTIONS

- Most common adverse reactions (incidence > 20%) are hypersensitivity reactions including anaphylaxis, nasopharyngitis, pyrexia, headache, and arthralgia.

USE IN SPECIFIC POPULATION

- Pregnancy: Based on findings from animal reproduction studies, Lamzede™ may cause embryo-fetal harm when administered to a pregnant female.
- Lactation: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Lamzede™ and any potential adverse effects on the breastfed infant from velmanase alfa-tycv or from the underlying maternal condition.
- Females and Males of Reproductive Potential: For females of reproductive potential, verify that the patient is not pregnant prior to initiating treatment with Lamzede™. Advise females of reproductive potential to use effective contraception during treatment and for 14 days after the last dose if Lamzede™ is discontinued.

DRUG NAME	MANUFACTURER	APPROVAL DATE
FILSPARI™ (SPARSENTAN) TABLETS	TRAVERE THERAPEUTICS, INC.	2/17/2023

THERAPEUTIC CLASS
Genitourinary Agents

FDA-APPROVED INDICATION(S)
Filspari™ is an endothelin and angiotensin II receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

DOSAGE AND ADMINISTRATION
- Prior to initiating treatment with Filspari™, discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs) or aliskiren.
- Initiate treatment with Filspari™ at 200 mg orally once daily. After 14 days, increase to the recommended dose of 400 mg once daily, as tolerated. When resuming treatment with Filspari™ after an interruption, consider titration of Filspari™, starting at 200 mg once daily. After 14 days, increase to the recommended dose of 400 mg once daily.
- Instruct patients to swallow tablets whole with water prior to the morning or evening meal.

DOSAGE FORMS AND STRENGTHS
Tablets: 200mg and 400mg

SAFETY PROFILE

CONTRAINDICATIONS
- Pregnancy.
- Do not coadminister Filspari™ with angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren.

WARNINGS AND PRECAUTIONS
- **BLACK BOX WARNING**: HEPATOTOXICITY AND EMBRYO-FETAL TOXICITY
  - Filspari™ is only available through a restricted distribution program called the FILSPARI Risk Evaluation and Mitigation Strategies (REMS) because of these risks.
  - Some endothelin receptor antagonists have caused elevations of aminotransferases, hepatotoxicity, and liver failure.
  - Measure liver aminotransferases and total bilirubin prior to initiation of treatment and ALT and AST monthly for 12 months, then every 3 months during treatment.
  - Interrupt treatment and closely monitor patients developing aminotransferase elevations more than 3x Upper Limit of Normal (ULN).
  - Based on animal data, Filspari™ can cause major birth defects if used during pregnancy.
  - Pregnancy testing is required before, during, and after treatment.
  - Patients who can become pregnant must use effective contraception prior to initiation of treatment, during treatment, and for one month after.

WARNINGS AND PRECAUTIONS (CONT.)
- Hepatotoxicity
- Embryo-Fetal Toxicity
- Hypotension
- Acute Kidney Injury
- Hyperkalemia
- Fluid Retention

ADVERSE REACTIONS
- Most common adverse reactions (≥5%) are peripheral edema, hypotension (including orthostatic hypotension), dizziness, hyperkalemia, and anemia.

DRUG INTERACTIONS
- Renin-Angiotensin System (RAS) inhibitors and ERAs: Contraindicated. Increased risk of hypotension, hyperkalemia.
- Strong CYP3A inhibitors: Avoid concomitant use. Increased sparsentan exposure.
- Moderate CYP3A inhibitors: Monitor adverse reactions. Increased sparsentan exposure.
- Strong CYP3A inducers: Avoid concomitant use. Decreased sparsentan exposure.

Orphan status: Yes

DRUG NAME	MANUFACTURER	APPROVAL DATE
FILSPARI™ (SPARSENTAN) TABLETS	TRAVERE THERAPEUTICS, INC.	2/17/2023

THERAPEUTIC CLASS
Genitourinary Agents

FDA-APPROVED INDICATION(S)
Filspari™ is an endothelin and angiotensin II receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

DOSAGE AND ADMINISTRATION
- Prior to initiating treatment with Filspari™, discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs) or aliskiren.
- Initiate treatment with Filspari™ at 200 mg orally once daily. After 14 days, increase to the recommended dose of 400 mg once daily, as tolerated. When resuming treatment with Filspari™ after an interruption, consider titration of Filspari™, starting at 200 mg once daily. After 14 days, increase to the recommended dose of 400 mg once daily.
- Instruct patients to swallow tablets whole with water prior to the morning or evening meal.

DOSAGE FORMS AND STRENGTHS
Tablets: 200mg and 400mg

SAFETY PROFILE

DRUG INTERACTIONS (CONT.)
- Antacids: Avoid use within 2 hours before or after use of sparsentan. May decrease exposure to sparsentan.
- Acid reducing agents: Avoid concomitant use. May decrease exposure to sparsentan.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) including selective cyclooxygenase (COX-2) inhibitors: Monitor for signs of worsening renal function. Increased risk of kidney injury.
- CYP2B6, 2C9, and 2C19 substrates: Monitor for efficacy of the concurrently administered substrates. Decreased exposure of these substrates.
- Sensitive P-gp and BCRP substrates: Avoid concomitant use. Increased exposure to substrates.
- Agents Increasing Serum Potassium: Increased risk of hyperkalemia, monitor serum potassium frequently.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on data from animal reproductive toxicity studies, Filspari™ can cause fetal harm, including birth defects and fetal death, when administered to a pregnant patient and is contraindicated during pregnancy.
- Lactation: Because of the potential for adverse reactions, such as hypotension in breastfed infants, advise patients not to breastfeed during treatment with Filspari™.
- Females and Males of Reproductive Potential: Verify that patients who can become pregnant are not pregnant prior to initiating Filspari™, monthly during treatment, and one month after discontinuation of treatment. The patient should contact their physician immediately for pregnancy testing if onset of menses is delayed or pregnancy is suspected. If the pregnancy test is positive, the physician and patient must discuss the risks to their pregnancy and the fetus. Patients who can become pregnant who are using Filspari™ must use an effective method of contraception prior to initiation of treatment, during treatment, and for one month after discontinuation of treatment with Filspari™ to prevent pregnancy
- Hepatic Impairment: Avoid use of Filspari™ in patients with any hepatic impairment (Child-Pugh class A-C) because of the potential risk of serious liver injury.

Orphan status: Yes

DRUG NAME	MANUFACTURER	APPROVAL DATE
SKYCLARYS™ (OMAVELOXOLONE) CAPSULES	REATA PHARMACEUTICALS INC.	2/28/2023

THERAPEUTIC CLASS
Neuromuscular Agents

FDA-APPROVED INDICATION(S)
Skyclarys™ is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

DOSAGE AND ADMINISTRATION
- Obtain alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, B-type natriuretic peptide (BNP), and lipid parameters prior to initiating Skyclarys™ and during treatment.
- Recommended dosage is 150 mg (3 capsules) taken orally once daily.
- Administer Skyclarys™ on an empty stomach at least 1 hour before eating.
- Swallow Skyclarys™ capsules whole. Do not open, crush or chew.
- Moderate and Severe Hepatic Impairment: The recommended dosage of Skyclarys™ is 100 mg once daily for patients with moderate hepatic impairment. If adverse reactions emerge, further reduce the dosage to 50 mg once daily.

DOSAGE FORMS AND STRENGTHS
Capsules: 50mg

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Elevation of Aminotransferases: Monitor ALT, AST, and total bilirubin prior to initiation, every month for the first 3 months of treatment, and periodically thereafter.
- Elevation of B-type Natriuretic Peptide (BNP): Advise patients of signs and symptoms of fluid overload.
- Lipid Abnormalities: Monitor cholesterol periodically during treatment.

ADVERSE REACTIONS
- Most common adverse reactions (incidence ≥20% and greater than placebo) are elevated liver enzymes (AST/ALT), headache, nausea, abdominal pain, fatigue, diarrhea, and musculoskeletal pain.

DRUG INTERACTIONS
- Moderate or Strong CYP3A4 Inhibitors: Avoid concomitant use. Consider Skyclarys™ dosage reduction with monitoring if use is unavoidable.
- Moderate or Strong CYP3A4 Inducers: Avoid concomitant use.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on animal data, may cause fetal harm.
- Lactation: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Skyclarys™ and any potential adverse effects on the breastfed infant from Skyclarys™ or from the underlying maternal condition.
- Females and Males of Reproductive Potential: Skyclarys™ may decrease the efficacy of hormonal contraceptives. Advise patients to avoid concomitant use with combined hormonal contraceptives (e.g., pill, patch, ring), implants, and progestin only pills. Counsel females using hormonal contraceptives to use an alternative contraceptive method (e.g., non-hormonal intrauterine system) or additional non-hormonal contraceptive (e.g., condoms) during concomitant use and for 28 days after discontinuation of Skyclarys™.
- Hepatic Impairment: Avoid treatment with Skyclarys™ in patients with severe hepatic impairment, including those who develop severe hepatic impairment. If hepatic function improves to moderate impairment, mild impairment, or normal function, initiation of Skyclarys™ treatment at the approved recommended dosage may be considered.

Orphan status: Yes

New Biosimilar Products

- No new biosimilar product was approved in February.

New Formulations, Combination Products & Line Extensions

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Atorvaliq™ (atorvastatin calcium) oral suspension / CMP DEV LLC	2/1/2023	Antihyperlipidemics	[1] To reduce the risk of: (A) Myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD, (B) MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD, (C) Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure (CHF), and angina in adults with clinically evident CHD; [2] As an adjunct to diet to reduce low-density lipoprotein (LDL-C) in: (A) Adults with primary hyperlipidemia, (B) Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH); [3] As an adjunct to other LDL-C lowering therapies to reduce LDL-C in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia; [4] As an adjunct to diet for the treatment of adults with: (A) Primary dysbetalipoproteinemia, (B) Hypertriglyceridemia	Atorvaliq™ is the first oral suspension formulation of atorvastatin. It shares the same indications as atorvastatin tablets. CMP Pharma's launch plans for Atorvaliq™ are pending. Atorvaliq™ will be available as a 20 mg/5 mL oral suspension. Orphan: No

New Formulations, Combination Products & Line Extensions

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Austedo™ XR (deutetrabenzine) extended-release tablets / Teva Neuroscience Inc.	2/17/2023	Central Nervous System Agents	Treatment of: [1] Chorea associated with Huntington's disease; [2] Tardive dyskinesia	This is a new once-daily formulation of deutetrabenzine. It boasts therapeutic equivalence to its twice-a-day counterpart. Orphan: No
Syfovre™ (pegcetacoplan) injection / Apellis Pharmaceuticals Inc.	2/17/2023	Ophthalmic Agents	Treatment of geographic atrophy (GA) secondary to age-related macular degeneration.	This is the first and only treatment for GA, a leading clause of blindness. It is expected to be available by the beginning of March through specialty distributors and specialty pharmacies. Orphan: No
Prevduo™ (neostigmine methylsulfate and glycopyrrolate) injection / Slayback Pharma LLC	2/23/2023	Antimyasthenic/ Cholinergic Agents	For the reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery, while decreasing the peripheral muscarinic effects (e.g., bradycardia and excessive secretions) associated with cholinesterase inhibition following NMBA reversal administration in patients aged two years and above	This is a fixed-dose combination of a cholinesterase inhibitor and antimuscarinic agent. Orphan: No

New First-Time Generic Approvals

Product	Manufacturer	Approval Date	Generic For:	Therapeutic Class	Indication(s)
Doxepin hydrochloride topical cream 5%	Teva Pharmaceuticals USA, Inc.	2/17/2023	Zonalon™	Dermatologicals – Antipruritics	Pruritus
Tiopronin delayed release tablets 100mg and 300mg	Par Pharmaceutical, Inc.	2/24/2023	Thiola™ EC	Genitourinary Agents	Cystinuria

New FDA-Approved Indications for Existing Drugs

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Takhzyro™ (lanadelumab-flyo) injection / Takeda Pharmaceutical USA Inc.	Immunological agents	For prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years and older	For prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older	2/3/2023
Trodelvy™ (sacituzumab govitecan-hziy) injection / Gilead Sciences Inc.	Antineoplastics	[1] Unresectable locally advanced or metastatic triple-negative breast cancer who have received 2 or more prior systemic therapies, at least one of them for metastatic disease; [2] Locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor	Unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting	2/3/2023
Eylea™ (aflibercept) injection / Regeneron Pharmaceuticals Inc.	Ophthalmic agents	[1] Neovascular (wet) age-related macular degeneration; [2] Macular edema following retinal vein occlusion; [3] Diabetic macular edema and diabetic retinopathy	Retinopathy of prematurity	2/8/2023

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Cibinqo™ (abrocitinib) tablets / Pfizer Inc.	Immunological Agents	Treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable	Treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable	2/9/2023

Pipeline

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
OX124 (naloxone) / Orexo AB	2/3/2023	Opioid overdose	OX124, a nasal rescue medication, is based on Orexo's drug delivery platform amorphOX® and contains a high-dose of naloxone. It is designed to reverse the effects of powerful synthetic opioids, such as fentanyl. If approved, the US launch is expected to be initiated in the first half of 2024. NDA submitted.	Moderate
Zuranolone / Biogen Inc. and Sage Therapeutics Inc.	2/6/2023	Major depressive disorder (MDD) and postpartum depression (PPD)	Zuranolone is an investigational drug being evaluated as a 14-day, rapid-acting, once-daily, oral treatment in adults with MDD and PPD. The application has been granted priority review and the FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of August 5, 2023. NDA accepted.	Moderate
Reproxalap / Aldeyra Therapeutics Inc.	2/7/2023	Treatment of signs and symptoms of dry eye disease	Reproxalap is a first-in-class investigational new drug candidate for the treatment of dry eye disease. The FDA assigned a PDUFA date of November 23, 2023. NDA accepted.	High

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
ATI-1501 (metronidazole) / Appili Therapeutics Inc. and Saptalis Pharmaceuticals LLC	2/8/2023	Parasitic and anaerobic bacterial infections	ATI-1501 is a proprietary taste-masked liquid suspension reformulation of metronidazole. It is designed to enable broader use of metronidazole and provide a solution with the same safety and efficacy profile provided by metronidazole, thereby helping patients to adhere with their medication and improve their prognoses. The FDA established a PDUFA action date of September 23, 2023. NDA accepted.	Moderate
Nyxol™ (phentolamine ophthalmic solution 0.75%) / Ocuphire Pharma Inc.	2/13/2023	Treatment for reversal of pharmacologically induced mydriasis	Nyxol™ is a proprietary, preservative-free, stable, investigational eye drop formulation of phentolamine ophthalmic solution 0.75% designed to uniquely modulate the pupil size by blocking the α1 receptors found only on the iris dilator muscle without affecting the ciliary muscle. The FDA assigned a PDUFA date of September 28, 2023. NDA accepted.	Moderate

Pipeline

Drug Name and Manufacturer/	Date	Indication(s)	Additional Information	Impact
CSF-1 / Orasis Pharmaceuticals	2/21/2023	Treatment of presbyopia	CSF-1 is a proprietary, preservative-free formulation of low-dose pilocarpine designed to achieve an optimal balance between efficacy, safety and comfort. The FDA has assigned a PDUFA goal date of October 22, 2023. NDA accepted.	Moderate
Pozelimab / Regeneron Pharmaceuticals Inc.	2/21/2023	Treatment for adults and children as young as 1 year of age with CHAPLE disease (CD55 deficiency with Hyperactivation of complement, Angiopathic thrombosis and Protein Losing Enteropathy or CD55-deficient protein-losing enteropathy)	Pozelimab was invented using Regeneron's proprietary VelocImmune® technology and is an investigational, fully human, monoclonal antibody designed to block the activity of complement factor C5 and prevent diseases mediated by the complement pathway. It was granted Orphan Drug and Fast Track Designation. The target action date for the FDA decision is August 20, 2023. BLA accepted.	High high
Elranatamab / Pfizer Inc.	2/22/2023	Treatment of patients with relapsed or refractory multiple myeloma	The FDA has granted Priority Review for elranatamab, an investigational B-cell maturation antigen CD3-targeted bispecific antibody. In addition, the FDA has granted Breakthrough Therapy Designation and Orphan Drug Designation. BLA accepted.	High high

Pipeline

Drug Name and Manufacturer/	Date	Indication(s)	Additional Information	Impact
VP-102 / Verrica Pharmaceuticals Inc.	2/27/2023	Treatment of molluscum contagiosum	VP-102, is a proprietary drug-device combination product that contains a GMP-controlled formulation of cantharidin (0.7% w/v) delivered via a single-use applicator that allows for precise topical dosing and targeted administration. VP-102 could potentially be the first product approved by the FDA to treat molluscum contagiosum — a common, highly contagious skin disease that affects an estimated six million people in the United States. The FDA has given Verrica Pharmaceuticals a PDUFA date of July 23, 2023 NDA accepted.	High

References

- *New Drug Approvals*. Drugs.com. (2023). https://www.drugs.com/newdrugs.html.
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