PHARMNOTES

July 2023

Date: 8/9/2023

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Drug Safety Alert Notification

- No drug safety communication published in July.

New FDA-Approved Drug Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
BEYFORTUS™ (NIRVESIMAB-ALIP) INJECTION	ASTRAZENECA AB	7/17/2023

THERAPEUTIC CLASS
vaccines

FDA-APPROVED INDICATION(S)
Beyfortus™ is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease in:

- Neonates and infants born during or entering their first RSV season
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season

DOSAGE AND ADMINISTRATION

- Administer as an intramuscular injection
- Recommended dosage: Neonates and infants born during or entering their first RSV season:
  - 50 mg if less than 5 kg in body weight
  - 100 mg if greater than or equal to 5 kg in body weight.
- Children who remain vulnerable through their second RSV season: 200 mg (2 x 100 mg injections)

DOSAGE FORMS AND STRENGTHS
Injection:

- 50 mg/0.5 mL in a single-dose pre-filled syringe
- 100 mg/mL in a single-dose pre-filled syringe

SAFETY PROFILE

CONTRAINDICATIONS

- Contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients

WARNINGS AND PRECAUTIONS

- Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human IgG1 monoclonal antibodies. Initiate appropriate medications and/or supportive therapy

ADVERSE REACTIONS

- Most common adverse reactions were rash (0.9%) and injection site reactions (0.3%).

USE IN SPECIFIC POPULATIONS

- The safety and effectiveness of Beyfortus™ in children older than 24 months of age have not been established.

Orphan status: No

DRUG NAME	MANUFACTURER	APPROVAL DATE
VANFLYTA™ (QUIZARTINIB) TABLETS	DAIICHI SANKYO INC	7/20/2023

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
Vanflyta™ is a kinase inhibitor indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION
Select patients for the treatment of AML with Vanflyta™ based on the presence of FLT3-ITD mutation positivity.
A treatment course consists of up to 2 cycles of Vanflyta™ in combination with induction cytarabine and anthracycline, up to 4 cycles of Vanflyta™ in combination with high-dose cytarabine consolidation, and up to 36 cycles of Vanflyta™ as maintenance therapy or until disease progression or unacceptable toxicity.

- Induction dosage regimen: 35.4mg orally once daily starting on Day 8, two weeks in each cycle (Days 8-21)
- Consolidation dosage regimen: 35.4mg orally once daily starting on Day 6m two weeks in each cycle (Days 6-19)
- Maintenance dosage regimen: 26.5mg-53mg once daily with no break between cycles for up to 36 cycles

DOSAGE FORMS AND STRENGTHS
Tablets: 17.7 mg or 26.5 mg

SAFETY PROFILE

CONTRAINDICATIONS
- Contraindicated in patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, or in patients with a history of ventricular arrhythmias or torsades de pointes

WARNINGS AND PRECAUTIONS
- **BLACK BOX WARNING: QT PROLONGATION, TORSADES DE POINTES AND CARDIAC ARREST**
  - Vanflyta™ prolongs the QT interval. Prior to Vanflyta™ administration and periodically, perform electrocardiograms (ECGs), monitor for hypokalemia or hypomagnesemia, and correct deficiencies.
  - Torsades de pointes and cardiac arrest have occurred in patients receiving Vanflyta™. Do not administer Vanflyta™ to patients with severe hypokalemia, severe hypomagnesemia, or long QT syndrome.
  - Do not initiate treatment with Vanflyta™ or escalate the Vanflyta™ dose if the QT interval corrected by Fridericia's formula (QTcF) is greater than 450 ms.
  - Monitor ECGs more frequently if concomitant use of drugs known to prolong the QT interval is required.
  - Reduce the Vanflyta™ dose when used concomitantly with strong CYP3A inhibitors, as they may increase quizartinib exposure.
  - Vanflyta™ is available only through a restricted program called the Vanflyta™ Risk Evaluation and Mitigation Strategy (REMS).
- QT Prolongation, Torsades de Pointes, and Cardiac Arrest: Monitor electrocardiograms and levels of serum electrolytes. Reduce, interrupt, or permanently discontinue Vanflyta™ as appropriate.

WARNINGS AND PRECAUTIONS (CONT.)
- Embryo-Fetal Toxicity: Vanflyta™ can cause fetal harm. Advise females of reproductive potential and males with female partners of reproductive potential of potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS
The most common (>20%) adverse reactions, including laboratory abnormalities, are lymphocytes decreased, potassium decreased, albumin decreased, phosphorus decreased, alkaline phosphatase increased, magnesium decreased, febrile neutropenia, diarrhea, mucositis, nausea, calcium decreased, abdominal pain, sepsis, neutropenia, headache, creatine phosphokinase increased, vomiting, and upper respiratory tract infection.

DRUG INTERACTIONS
- Strong CYP3A Inhibitors: Reduce the Vanflyta™ dose.
- Strong or Moderate CYP3A Inducers: Avoid concomitant use.

USE IN SPECIFIC POPULATIONS
- **Pregnancy:** Can cause embryo-fetal harm when administered to a pregnant woman.
- **Lactation:** Advise women not to breastfeed during treatment with VANFLYTA and for one month after the last dose.
- **Females and Males of Reproductive Potential:** Verify pregnancy status in females of reproductive potential within seven days before starting treatment. Advise female patients of reproductive potential to use effective contraception during treatment with Vanflyta™ and for 7 months after the last dose. Based on genotoxicity findings, advise male patients with female partners of reproductive potential to use effective contraception during treatment with Vanflyta™ and for 4 months after the last dose.

Orphan status: Yes

DRUG NAME	MANUFACTURER	APPROVAL DATE
YCANTH™ (CANTHARIDIN) TOPICAL SOLUTION	VERRICA PHARMS	7/21/2023

THERAPEUTIC CLASS
Dermatologicals

FDA-APPROVED INDICATION(S)
Ycanth™ is indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.

DOSAGE AND ADMINISTRATION
- All healthcare professionals should receive instruction and training prior to preparation and administration of Ycanth™.
- For topical use only. Not for oral, mucosal, or ophthalmic use.
- Apply a single application directly to each lesion every 3 weeks as needed.
- Do not use more than two applicators during a single treatment session.
- Remove with soap and water 24 hours after treatment.
- For additional instructions on preparation and administration of Ycanth™, see Full Prescribing Information.

DOSAGE FORMS AND STRENGTHS
Topical solution: 0.7% cantharidin

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Toxicities Associated with Inappropriate Administration: Life threatening or fatal toxicities can occur if administered orally. Avoid contact with the treatment area, including oral contact, after treatment. Ocular toxicity can occur if Ycanth™ comes in contact with eyes. If Ycanth™ gets in eyes, flush eyes with water for at least 15 minutes.
- Local Skin Reactions: Reactions at the application site have included vesiculation, pruritus, pain, discoloration, and erythema. Avoid application near eyes and mucosal tissue, and to healthy skin. If Ycanth™ contacts any unintended surface, or healthy skin, immediately remove. If severe local skin reactions occur, remove prior to 24 hours after treatment.
- Flammability: Ycanth™ is flammable, even after drying. Avoid fire, flame or smoking near lesion(s) during treatment and after application until removed.

ADVERSE REACTIONS
Most common (incidence ≥1%) adverse reactions are the following local skin reactions at the application site: vesiculation, pain, pruritus, scabbing, erythema, discoloration, application site dryness, edema, and erosion.

DRUG NAME	MANUFACTURER	APPROVAL DATE
XDEMVY™ (LOTILANER OPHTHALMIC SOLUTION) 0.25%	VERRICA PHARMS	7/21/2023

THERAPEUTIC CLASS
Ophthalmic agents

FDA-APPROVED INDICATION(S)
Xdemvy™ is an ectoparasiticide (anti-parasitic) indicated for the treatment of Demodex blepharitis.

DOSAGE AND ADMINISTRATION
Instill one drop of Xdemvy™ in each eye twice daily (approximately 12 hours apart) for 6 weeks.

DOSAGE FORMS AND STRENGTHS
Ophthalmic solution containing lotilaner 0.25%.

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Risk of Contamination: Do not allow the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to minimize contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.
- Use with Contact Lenses: Contact lenses should be removed prior to instillation of Xdemvy™ and may be reinserted 15 minutes following its administration.

ADVERSE REACTIONS
The most common adverse reaction was instillation site stinging and burning (10%).

Orphan status: No

New Biosimilar Products

- No biosimilar product approved by the FDA in July.

New Formulations, Combination Products & Line Extensions

Drug Name and Manufacturer	Date	Therapeutic Class	Indication(s)	Additional Information
Opill™ (norgestrel) tablets / Perrigo Company	7/13/2023	Contraceptives	For use by females of reproductive potential to prevent pregnancy	Opill is a progrestin-only daily oral contraceptive and the first birth control pill available over-the-counter in the United States. Orphan: No
Balfaxar™ (prothrombin complex concentrate, human-lans) lyophilized powder for solution / Octapharma USA	7/21/2023	Hematological agents	For the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist therapy in adult patients with need for an urgent surgery/invasive procedure	Balfaxar™ is a non-activated four-factor prothrombin complex concentrate (4F-PCC) that is provided as a lyophilized powder for reconstitution, along with a new transfer device, Nextaro®. Orphan: No
RiVive™ (naloxone hydrochloride) nasal spray / Harm Reduction Therapeutics	7/28/2023	Antidotes	Treatment of known or suspected opioid overdose	RiVive™ is the second over-the-counter naloxone nasal spray product approved by the FDA. It contains 3mg of naloxone hydrochloride. Orphan: No

New First-Time Generic Approvals

Product	Manufacturer	Approval Date	Generic For:	Therapeutic Class	Indication(s)	Projected Launch Date
Naltrexone for extended-release injectable suspension 380mg/vial	Teva Pharmaceuticals USA, Inc.	7/6/2023	Vivitrol™	Antidotes	[1] Alcohol dependence; [2] Opioid dependence	2H 2024
Ertugliflozin tablets 5mg and 15mg	Aurobindo Pharma Limited	7/13/2023	Steglatro™	Antidiabetics	Type 2 diabetes mellitus	4Q 2031
Ponatinib hydrochloride tablets 15mg (base) and 45mg (base)	ApoPharma USA, Inc.	7/14/2023	Iclusig™	Antineoplastics	[1] Chronic myeloid leukemia; [2] Acute lymphoblastic leukemia	2029-2030
Plerixafor injection 24mg/1.2mL (20mg/mL)	Amneal Pharmaceuticals LLC; Dr. Reddy's Laboratories, Inc.; Eugia Pharma Specialties Ltd; Kindos Pharmaceuticals Co. Ltd; MSN Laboratories Private Ltd.; Teva Pharmaceuticals USA, Inc.	7/24/2023	Mozobil™	Hematopoietic agents	Peripheral blood progenitor cell therapy	Launched

New First-Time Generic Approvals

Product	Manufacturer	Approval Date	Generic For:	Therapeutic Class	Indication(s)	Projected Launch Date
Saxagliptin hydrochloride tablets 2.5mg (base) and 5mg (base)	Amneal Pharmaceuticals LLC; Aurobindo Pharma Limited; Glenmark Pharmaceuticals Inc.; Mylan Pharmaceuticals Inc.; Sun Pharmaceutical Industries, Inc.	7/31/2023	Onglyza™	Antidiabetics	Type 2 diabetes mellitus	2H 2023
Saxagliptin hydrochloride and metformin hydrochloride extended-release tablets 5mg (base)/500mg, 5mg (base)/1000mg, 2.5mg (base)/1000mg	Mylan Pharmaceuticals Inc.; Sun Pharmaceutical Industries, Inc.	7/31/2023	Kombiglyze™ XR	Antidiabetics	Type 2 diabetes mellitus	2H 2023

New FDA-Approved Indications for Existing Drugs

New FDA-Approved Indications

Drug Name and Manufacturer	Therapeutic Class	Previous Indication(s)	New Indication(s)	Date
Leqvio™ (inclisiran) injection / Novartis	Antihyperlipidemics	As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C)	As an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C)	7/7/2023
Ervebo™ (ebola zaire vaccine, live) suspension for intramuscular injection / Merck	Vaccines	For the prevention of disease caused by Zaire ebolavirus in individuals 18 years of age and older	For the prevention of disease caused by Zaire ebolavirus in individuals 12 months of age and older	7/27/2023
Jemperli™ (dostarlimab-gxly) injection / GlaxoSmithKline	Antineoplastics	Treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced: endometrial cancer or solid tumors	In combination with carboplatin and paclitaxel, followed by Jemperli as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H)	7/31/2023

Pipeline

Pipeline

Drug Name and Manufacturer	Date	Indication(s)	Additional Information	Impact
Rivoceranib / Elevar Therapeutics, Inc.	7/17/2023	In combination with camrelizumab, a PD-1 inhibitor, as a first-line treatment option for unresectable hepatocellular carcinoma (uHCC)	Rivoceranib is an oral tyrosine kinase inhibitor and the combination of this molecule with camrelizumab has demonstrated statistically significant and clinically meaningful prolonged overall survival (OS) and progression-free survival (PFS), and improved overall response comparted to standard first-line treatment for uHCC. The FDA assigned a Prescription Drug User Fee Act (PDUFA) target action date of May 16, 2024 NDA accepted.	High high
Resmetirom / Madrigal Pharmaceuticals, Inc.	7/17/2023	Treatment of adults with nonalcoholic steatohepatitis (NASH)	Resmetirom is a once daily, oral, thyroid hormone receptor (THR)-β selective agonist designed to target key underlying causes of NASH in the liver. NDA submitted.	High

References

- *New Drug Approvals*. Drugs.com. (2023). https://www.drugs.com/newdrugs.html.
- *Latest Generic Drug Approvals*. Drugs.com. (2023). https://www.drugs.com/generic-approvals.html.
- *New Indications & Dosage Forms for Existing Drugs*. Drugs.com. (2023). https://www.drugs.com/new-indications.html.
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