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PharmNOTES

Summary of New FDA-Approved Products,
New Indications, First-Time Generics,
and WHAT'S IN THE PIPELINE
For: **SEPTEMBER 2022**

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

Date: 10/7/2022

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NEWS

- No drug safety alert published by the FDA in September.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
SPEVIGO™ (SPESOLIMAB-SBZO) INJECTION	BOEHRINGER INGELHEIM PHARMACEUTICALS INC.	9/1/2022

THERAPEUTIC CLASS
Dermatologicals

FDA-APPROVED INDICATION(S)
Spevigo™ is an interleukin-36 receptor antagonist indicated for the treatment of generalized pustular psoriasis flares in adults.

DOSAGE AND ADMINISTRATION
Administer as a single 900mg dose by intravenous infusion over 90 minutes. If flare symptoms persist, may administer an additional intravenous 900mg dose one week after the initial dose.

DOSAGE FORMS AND STRENGTHS
Injection: 450mg/7.5mL (60mg/mL) solution in a single-dose vial

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS
- Severe or life-threatening hypersensitivity to spesolimab-sbzo or to any of the excipients in Spevigo™

WARNINGS AND PRECAUTIONS
- Infections: Spevigo™ may increase the risk of infections. Do not initiate Spevigo™ during any clinically important active infection. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur after treatment with Spevigo™.
- Tuberculosis (TB): Evaluate patients for TB prior to initiating treatment with Spevigo™.
- Hypersensitivity and Infusion-Related Reactions: Hypersensitivity including drug reaction with eosinophilia and systemic symptoms (DRESS) and infusion-related reactions may occur. If a serious hypersensitivity reaction occurs, discontinue Spevigo™ immediately and initiate appropriate treatment.
- Vaccinations: Do not administer live vaccines concurrently with Spevigo™.

ADVERSE REACTIONS
- Most common adverse reactions (≥5%) are asthenia and fatigue, nausea and vomiting, headache, pruritus and prurigo, infusion site hematoma and bruising, and urinary tract infection.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Limited data on the use of Spevigo™ in pregnant women are insufficient to inform a drug-associated risk of adverse pregnancy-related outcomes.
- Pediatric Use: The safety and effectiveness of Spevigo™ in pediatric patients have not been established.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
DAXXIFY™ (DAXIBOTULINUMTOXINA-LANM) INJECTION	REVANCE THERAPEUTICS, INC.	9/7/2022

THERAPEUTIC CLASS
Neuromuscular agents

FDA-APPROVED INDICATION(S)
Daxxify™ is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

DOSAGE AND ADMINISTRATION
Glabellar Lines: 0.1 mL (8 Units) by intramuscular injection into each of five sites, for a total dose of 40 Units.

DOSAGE FORMS AND STRENGTHS
For injection: 50 Units or 100 Units sterile lyophilized powder in a single-dose vial.

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to any botulinum toxin preparation,
- Daxxify™ or any of the components in the Daxxify™ formulation
- Infection at the injection sites

WARNINGS AND PRECAUTIONS
- **BLACK BOX WARNING: DISTANT SPREAD OF TOXIN EFFECT**
  - The effects of Daxxify™ and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. Daxxify™ is not approved for the treatment of spasticity or any conditions other than glabellar lines.
- The potency Units of Daxxify™ are not interchangeable with other preparations of other botulinum toxin products.
- Spread of toxin effects, swallowing and breathing difficulties can lead to death. Seek immediate medical attention if respiratory, speech or swallowing difficulties occur.

WARNING AND PRECAUTIONS (CONT.)
- Adverse event reports have been received involving the cardiovascular system with botulinum toxin products, some with fatal outcomes. Use caution when administering to patients with pre-existing cardiovascular disease.
- Concomitant neuromuscular disorder may exacerbate clinical effects of treatment.
- Use with caution in patients with compromised respiratory function or dysphagia.
- Potential serious adverse reactions after administration of Daxxify™ for unapproved use.

ADVERSE REACTIONS
- The most commonly observed adverse reactions (≥1%) are headache (6%), eyelid ptosis (2%) and facial paresis (1%).

USE IN SPECIFIC POPULATIONS
- Pediatric Use: Safety and effectiveness of Daxxify™ in patients less than 18 years of age have not been established.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
SOTYKTU™ (DEUCRAVACITINIB) TABLET	BRISTOL MYERS INC.	9/9/2022

THERAPEUTIC CLASS
Dermatologicals

FDA-APPROVED INDICATION(S)
Sotyktu™ is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

DOSAGE AND ADMINISTRATION
- For recommended evaluation prior to SOTYKTU initiation, see Full Prescribing Information.
- Recommended dosage is 6 mg orally once daily, with or without food.

DOSAGE FORMS AND STRENGTHS
Tablets: 6mg

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to deucravacitinib or any of the excipients in Sotyktu™.

WARNINGS AND PRECAUTIONS
- Hypersensitivity: Hypersensitivity reactions such as angioedema have been reported. Discontinue if a clinically significant hypersensitivity reaction occurs.
- Infections: Sotyktu™ may increase the risk of infection. Avoid use in patients with active or serious infection. If a serious infection develops, discontinue SOTYKTU until the infection resolves.
- Tuberculosis: Evaluate for TB prior to initiating treatment with Sotyktu™.
- Malignancy: Malignancies including lymphomas were observed in clinical trials with Sotyktu™
- Rhabdomyolysis and elevated CPK.
- Laboratory Abnormalities: Periodically evaluate serum triglycerides. Evaluate liver enzymes at baseline and thereafter in patients with known or suspected liver disease.
- Immunizations: Avoid use with live vaccines.

WARNING AND PRECAUTIONS (CONT.)
- Potential Risks Related to JAK Inhibition: It is not known whether TYK2 inhibition may be associated with the observed or potential adverse reactions of JAK inhibition. Higher rates of all-cause mortality, including sudden cardiovascular death, major adverse cardiovascular events, overall thrombosis, deep venous thrombosis, pulmonary embolism, and malignancies (excluding non-melanoma skin cancer) were observed in patients treated with a JAK inhibitor compared to those treated with TNF blockers in rheumatoid arthritis (RA) patients. Sotyktu™ is not approved for use in RA.

ADVERSE REACTIONS
- Most common adverse reactions (≥ 1%) are upper respiratory infections, blood creatine phosphokinase increased, herpes simplex, mouth ulcers, folliculitis, and acne.

USE IN SPECIFIC POPULATIONS
- Pediatric Use: The safety and effectiveness of Sotyktu™ in pediatric patients have not been established.
- Hepatic Impairment: Sotyktu™ is not recommended for use in patients with severe hepatic impairment (Child-Pugh C).

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
ROLVEDON™ (EFLAPEGRASTIM-XNST) INJECTION	SPECTRUM PHARMS	9/9/2022

THERAPEUTIC CLASS
Hematopoietic agents

FDA-APPROVED INDICATION(S)
Rolvedon™ is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.

DOSAGE AND ADMINISTRATION
Recommended Dose: 13.2 mg administered subcutaneously once per chemotherapy cycle.

Administer approximately 24 hours after cytotoxic chemotherapy. Do not administer within the period from 14 days before to 24 hours after administration of cytotoxic chemotherapy.

DOSAGE FORMS AND STRENGTHS
Injection: 13.2 mg/0.6 mL solution in a single-dose prefilled syringe.

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- Patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as eflapegrastim, pegfilgrastim or filgrastim products.

WARNINGS AND PRECAUTIONS
- Fatal splenic rupture: Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.
- Acute respiratory distress syndrome (ARDS): Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue Rolvedon™ in patients with ARDS.
- Serious allergic reactions, including anaphylaxis: Permanently discontinue Rolvedon™ in patients with serious allergic reactions.
- Sickle Cell Crisis in Patients with Sickle Cell Disorders: Discontinue Rolvedon™ if sickle cell crisis occurs.
- Glomerulonephritis: Evaluate and consider dose-reduction or interruption of Rolvedon™ if causality is likely.
- Leukocytosis: Monitor complete blood count (CBC) during Rolvedon™ therapy.
- Thrombocytopenia: Monitor platelet counts.
- Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML): Monitor patients with breast and lung cancer using Rolvedon™ in conjunction with chemotherapy and/or radiotherapy for signs and symptoms of MDS/AML.

ADVERSE REACTIONS
- The most common adverse reactions (≥20%) are fatigue, nausea, diarrhea, bone pain, headache, pyrexia, anemia, rash, myalgia, arthralgia, and back pain.

USE IN SPECIFIC POPULATIONS
- Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
TERLIVAZ™ (TERLIPRESSIN ACETATE) INJECTION	MALLINCKRODT IRELAND	9/14/2022

THERAPEUTIC CLASS
Endocrine and metabolic agents

FDA-APPROVED INDICATION(S)
Terlivaz™ is a vasopressin receptor agonist indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function.

DOSAGE AND ADMINISTRATION
Days 1 to 3 administer Terlivaz™ 0.85 mg (1 vial) intravenously every 6 hours
Day 4: Assess serum creatinine (SCr) versus baseline.

If SCr has decreased by at least 30% from baseline, continue Terlivaz™ 0.85 mg (1 vial) intravenously every 6 hours. If SCr has decreased by less than 30% from baseline, dose may be increased to Terlivaz™ 1.7 mg (2 vials) intravenously every 6 hours. If SCr is at or above baseline value, discontinue Terlivaz™. Continue Terlivaz™ until 24 hours after two consecutive SCr ≤1.5 mg/dL values at least 2 hours apart or a maximum of 14 days.

DOSAGE FORMS AND STRENGTHS
For injection: Terlivaz™ 0.85 mg (1 vial) as a lyophilized powder in a single-dose vial for reconstitution.

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS
- In patients experiencing hypoxia or worsening respiratory symptoms
- In patients with ongoing coronary, peripheral, or mesenteric ischemia

WARNINGS AND PRECAUTIONS
- Serious or Fatal Respiratory Failure: Monitor patients for changes in respiratory status using pulse oximetry and regular clinical assessments. Actively manage intravascular volume overload and adjust Terlivaz™ therapy as appropriate.
- Ineligibility for Liver Transplant: Terlivaz™-related adverse reactions may make a patient ineligible for liver transplantation, if listed.
- Ischemic Events: Terlivaz™ is a vasoconstrictor and can cause ischemic events (cardiac, peripheral, or mesenteric) that may require dose interruption or discontinuation.
- Embryo-Fetal Toxicity: Terlivaz™ may cause fetal harm when used during pregnancy. Advise females of reproductive potential of the potential hazard to the fetus.

ADVERSE REACTIONS
- The most common adverse reactions (≥10%) include abdominal pain, nausea, respiratory failure, diarrhea, and dyspnea.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on findings from the published literature and on its mechanism of action, Terlivaz™ may cause fetal harm when administered to a pregnant woman.
- Lactation: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Terlivaz™ and any potential adverse effects on the breastfed child from Terlivaz™ or from the underlying maternal condition.
- Pediatric Use: Safety and effectiveness of Terlivaz™ have not been established in pediatric patients.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
ELUCIREM™ (GADOPICLENOL) INJECTION	GUERBET LLC	9/21/2022

THERAPEUTIC CLASS
Diagnostic products

FDA-APPROVED INDICATION(S)
Elucirem™ is a gadolinium-based contrast agent indicated in adult and pediatric patients aged 2 years and older for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity:
- The central nervous system (brain, spine and associated tissues)
- The body (head and neck, thorax, abdomen, pelvis and musculoskeletal system)

DOSAGE AND ADMINISTRATION
The recommended dose for adult and pediatric patients aged 2 years and older is 0.05mmol/kg actual body weight (equivalent to 0.1mL/kg) administered intravenously at approximately 2mL/sec.

DOSAGE FORMS AND STRENGTHS
Injection: 0.5 mmol/mL of gadopiclenol in single-dose vials, single-dose prefilled syringes, and pharmacy bulk packages.

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- History of hypersensitivity reactions to Elucirem™.

WARNINGS AND PRECAUTIONS
- **BLACK BOX WARNING: NEPHROGENIC SYSTEMIC FIBROSIS**
  - Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.
  - The risk for NSF appears highest among patients with: chronic, severe kidney disease (GFR < 30 mL/min/1.73 m2), or acute kidney injury.
  - Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (e.g., age > 60 years, hypertension, diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
  - For patients at highest risk for NSF, do not exceed the recommended Elucirem™ dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

WARNINGS AND PRECAUTIONS
- Nephrogenic Systemic Fibrosis has occurred in patients with impaired elimination of GBCAs. Higher than recommended dosing or repeat dosing appear to increase the risk.
- Hypersensitivity Reactions: Serious hypersensitivity reactions have occurred with GBCAs. Monitor patients closely for need of emergency cardiorespiratory support.
- Gadolinium Retention: Gadolinium is retained for months or years in brain, bone, and other organs.

ADVERSE REACTIONS
- Most common adverse reactions (incidence >0.2%) in patients who received Elucirem™ are injection site pain, headache, nausea, injection site warmth and coldness, dizziness, and localized swelling.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Use only if imaging is essential during pregnancy and cannot be delayed.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
OMLONTI™ (OMIDENEPAG ISOPROPYL) 0.002% OPHTHALMIC USE	SANTEN INC.	9/22/2022

THERAPEUTIC CLASS
Ophthalmic agents

FDA-APPROVED INDICATION(S)
Omlonti™ is a relatively selective prostaglandin E2 (EP2) receptor agonist, indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION
The recommended dosage is one drop in the affected eye(s) once daily in the evening.

DOSAGE FORMS AND STRENGTHS
Ophthalmic solution containing 0.002% (0.02 mg/mL) of omidenepag isopropyl

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Pigmentation
- Eyelash changes
- Ocular Inflammation
- Macular Edema

ADVERSE REACTIONS
- The most common adverse reactions with incidence ≥ 1% are conjunctival hyperemia (9%), photophobia (5%), vision blurred (4%), dry eye (3%), instillation site pain (3%), eye pain (2%), ocular hyperemia (2%), punctate keratitis (2%), headache (2%), eye irritation (1%), and visual impairment (1%).

USE IN SPECIFIC POPULATIONS
- Pediatric Use: The safety and effectiveness of Omlonti™ have not been established in pediatric patients.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
RELYVRIO™ (SODIUM PHENYLBUTYRATE AND SODIUM TAURURSODIOL) ORAL SUSPENSION	AMYLYX PHARMS	9/29/2022

THERAPEUTIC CLASS
Histone deacetylase inhibitor

FDA-APPROVED INDICATION(S)
Relyvrio™ is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults.

DOSAGE AND ADMINISTRATION
The recommended dosage is 1 packet (3 g sodium phenylbutyrate and 1 g taurursodiol) administered orally or via feeding tube as follows:

- Initial dosage: 1 packet daily for the first 3 weeks
- Maintenance dosage: 1 packet twice daily thereafter

Empty contents of one packet in a cup containing 8 ounces of room temperature water and stir vigorously prior to administration. Take within 1 hour of preparation. Administer Relyvrio™ before a snack or meal.

DOSAGE FORMS AND STRENGTHS
For oral suspension: 3 g sodium phenylbutyrate and 1 g taurursodiol in single-dose packets.

SAFETY PROFILE

CONTRAINDICATIONS

- None.

WARNINGS AND PRECAUTIONS

- Risk in Patients with Enterohepatic Circulation Disorders, Pancreatic Disorders, or Intestinal Disorders: In patients with disorders that interfere with bile acid circulation, consider consulting with a specialist. Monitor for new or worsening diarrhea in these patients. These conditions may also lead to decreased absorption of either of the components of Relyvrio™.
- Use in Patients Sensitive to High Sodium Intake: Relyvrio™ has a high sodium content. In patients sensitive to salt intake, consider the amount of daily sodium intake in each dose of Relyvrio™ and monitor appropriately.

ADVERSE REACTIONS

- Most common adverse reactions (at least 15% and at least 5% greater than placebo) are diarrhea, abdominal pain, nausea, and upper respiratory tract infection.

USE IN SPECIFIC POPULATIONS

- Pediatric Use: Safety and effectiveness of Relyvrio™ in pediatric patients have not been established.
- Renal Impairment: Avoid use in patients with moderate or severe renal impairment.
- Hepatic Impairment: Avoid use in patients with moderate or severe hepatic impairment.

Orphan status: Yes

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
LYTGOBI™ (FUTIBATINIB) TABLETS	TAIHO ONCOLOGY	9/30/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Lytgobi™ is a kinase inhibitor indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

DOSAGE AND ADMINISTRATION
- Confirm the presence of an FGFR2 gene fusion or other rearrangement prior to initiation of treatment with Lytgobi™.
- Recommended dose is 20 mg orally (five 4 mg tablets) once daily until disease progression or unacceptable toxicity occurs.
- Swallow tablet whole, with or without food.

DOSAGE FORMS AND STRENGTHS
Tablets: 4mg

Orphan status: Yes

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- Ocular Toxicity: Lytgobi™ can cause retinal pigment epithelial detachment (RPED). Perform a comprehensive ophthalmological examination including optical coherence tomography (OCT) prior to initiation of therapy, every 2 months for the first 6 months, and every 3 months thereafter and urgently at any time for visual symptoms.
- Hyperphosphatemia and Soft Tissue Mineralization: Increases in phosphate levels can cause hyperphosphatemia leading to soft tissue mineralization, calcinosis, nonuremic calciphylaxis and vascular calcification. Monitor for hyperphosphatemia and withhold, reduce the dose, or permanently discontinue based on duration and severity of hyperphosphatemia.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of reproductive potential of the potential risk to the fetus and to use effective contraception.

ADVERSE REACTIONS
- Most common (≥20%) adverse reactions were nail toxicity, musculoskeletal pain, constipation, diarrhea, fatigue, dry mouth, alopecia, stomatitis, abdominal pain, dry skin, arthralgia, dysgeusia, dry eye, nausea, decreased appetite, urinary tract infection, palmar-plantar erythrodysesthesia syndrome, and vomiting.
- Most common laboratory abnormalities (≥20%) were increased phosphate, increased creatinine, decreased hemoglobin, increased glucose, increased calcium, decreased sodium, decreased phosphate, increased alanine aminotransferase, increased alkaline phosphatase, decreased lymphocytes, increased aspartate aminotransferase, decreased platelets, increased activated partial thromboplastin time, decreased leukocytes, decreased albumin, decreased neutrophils, increased creatine kinase, increased bilirubin, decreased glucose, increased prothrombin international normalized ratio, and decreased potassium.

DRUG INTERACTIONS
- Dual P-gp and strong CYP3A inhibitors: Avoid coadministration.
- Dual P-gp and strong CYP3A inducers: Avoid coadministration.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
LYTGOBI™ (FUTIBATINIB) TABLETS	TAIHO ONCOLOGY	9/30/2022

THERAPEUTIC CLASS
Antineoplastics and adjunctive therapies

FDA-APPROVED INDICATION(S)
Lytgobi™ is a kinase inhibitor indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

DOSAGE AND ADMINISTRATION
- Confirm the presence of an FGFR2 gene fusion or other rearrangement prior to initiation of treatment with Lytgobi™.
- Recommended dose is 20 mg orally (five 4 mg tablets) once daily until disease progression or unacceptable toxicity occurs.
- Swallow tablet whole, with or without food.

DOSAGE FORMS AND STRENGTHS
Tablets: 4mg

Orphan status: Yes

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on findings in an animal study and its mechanism of action, Lytgobi™ can cause fetal harm or loss of pregnancy when administered to a pregnant woman.
- Lactation: Because of the potential for serious adverse reactions from Lytgobi™ in breastfed children, advise women not to breastfeed during treatment and for 1 week after the last dose.
- Females and Males of Reproductive Potential: Verify pregnancy status of females of reproductive potential prior to initiating Lytgobi™. Advise females of reproductive potential to use effective contraception during treatment with LYTGOBI and for 1 week after the last dose. Advise males with female partners of reproductive potential or who are pregnant to use effective contraception during treatment with LYTGOBI and for 1 week after the last dose.
- Pediatric Use: The safety and effectiveness of Lytgobi™ have not been established in pediatric patients.

NEW BIOSIMILAR PRODUCTS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	ADDITIONAL INFORMATION
STIMUFEND™ (PEGFILGRASTIM-FPGK) INJECTION / FRESENIUS KABI USA	Hematopoietic agents	To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	9/1/2022	Reference product: Neulasta™ (pegfilgrastim) Stimufend™ is the sixth pegfilgrastim biosimilar approved by the FDA. Fresenius Kabi expects to launch this biosimilar in a prefilled syringe in early 2023 and in an on-body injector following FDA approval. Orphan: No
VEGZELMA™ (BEVACIZUMAB-ADCD) INJECTION / CELLTRION INC.	Antineoplastics and adjunctive therapies	[1] Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment; [2] Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen; [3] Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment; [4] Recurrent glioblastoma in adults; [5] Metastatic renal cell carcinoma in combination with interferon alfa; [6] Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan; [7] Epithelial ovarian, fallopian tube, or primary peritoneal cancer	9/27/2022	Reference product: Avastin™ (bevacizumab) Vegzelma™ is the fourth bevacizumab biosimilar approved by the FDA. Celltrion has not yet announced the launch date and pricing of Vegzelma™. Orphan: No

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	ADDITIONAL INFORMATION
APONVIE™ (APREPITANT) INJECTABLE EMULSION / HERON THERAPEUTICS, INC.	Antiemetics	For the prevention of postoperative nausea and vomiting (PONV) in adults	9/16/2022	Aponvie™ is an intravenous formulation of aprepitant designed to deliver the agent in a 30-second IV injection. It is identical to the FDA-approved Cinvanti™ injectable emulsion formulation indicated for chemotherapy-induced nausea and vomiting. Orphan: No
PEDMARK™ (SODIUM THIOSULFATE) INJECTION / FENNEC PHARMACEUTICALS INC.	Chemotherapy rescue/antidote/ protective agents	To reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors	9/20/2022	Pedmark™ is the first and only FDA-approved therapy indicated to reduce the risk of cisplatin-associated ototoxicity. Orphan: Yes
IHEEZO™ (CHLOROPROCAINE HYDROCHLORIDE) OPHTHALMIC GEL / SINTETICA SA	Anesthetics	Ocular surface anesthesia	9/27/2022	Iheezo™ is a single-patient-use ophthalmic gel preparation indicated for administration under the direct supervision of a health care provider. Orphan: No

NEW FIRST-TIME GENERIC APPROVALS

GENERIC NAME/DOSAGE FORM/STRENGTH AND MANUFACTURER	GENERIC FOR:	THERAPEUTIC CLASS	INDICATIONS	APPROVAL DATE	PROJECTED LAUNCH DATE
RIOCIGUAT TABLETS 0.5MG, 1MG, 1.5MG, 2MG, 2.5MG / MSN LABORATORIES PRIVATE LTD.	Adempas™	Cardiovascular agents – misc.	Pulmonary hypertension	9/1/2022	4th quarter 2026
CARIPRAZINE HYDROCHLORIDE CAPSULES 1.5MG (BASE), 3MG (BASE), 4.5MG (BASE), 6MG (BASE) / ZYDUS PHARMACEUTICALS USA INC.	Vraylar™	Antipsychotics/antimanic agents	Schizophrenia	9/9/2022	2029-2030
TAZAROTENE TOPICAL GEL 0.05%, 0.1% / COSETTE PHARMACEUTICALS INC.	Tazorac™	Dermatologicals	Plaque psoriasis (0.05% strength) / Acne vulgaris (0.1% strength)	9/13/2022	Launched
NEBIVOLOL HYDROCHLORIDE AND VALSARTAN TABLETS 5MG-80MG / PRINSTON PHARMACEUTICAL INC.	Byvalson™	Antihypertensives	Hypertension	9/19/2022	2025-2026
GEFITINIB TABLETS 250MG / APOTEX INC.	Iressa™	Antineoplastics and adjunctive therapies	Non-small cell lung cancer	9/23/2022	4th quarter 2022

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NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
ORKAMBI™ (IVACAFTOR AND LUMACAFTOR) TABLETS AND ORAL GRANULES / VERTEX PHARMS INC	Respiratory agents	Treatment of cystic fibrosis (CF) in patients aged 2 years and older who are homozygous for the *F508del* mutation in the *CFTR* gene	Treatment of CF in patients aged 1 year and older who are homozygous for the *F508del* mutation in the *CFTR* gene	9/2/2022
IMFINZI™ (DURVALUMAB) INJECTION / ASTRAZENECA PHARMACEUTICALS	Antineoplastics and adjunctive therapies	[1] Treatment of adult patients with unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; [2] In combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)	In combination with gemcitabine and cisplatin, as treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC)	9/2/2022
RETEVMO™ (SELPERCARTINIB) CAPSULES / ELI LILLY AND CO.	Antineoplastics and adjunctive therapies	[1] Treatment of adult patients with locally advanced or metastatic NSCLC with a *rearranged during transfection (RET)* gene fusion, as detected by an FDA-approved test; [2] Treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a *RET* mutation, as detected by an FDA-approved test, who require systemic therapy; [3] Treatment of adult and pediatric 12 years of age and older with advanced metastatic thyroid cancer with a *RET* gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)	Treatment of adult patients with locally advanced or metastatic solid tumors with a *RET* gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options	9/21/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
DUPIXENT™ (DUPILUMAB) INJECTION / REGENERON PHARMACEUTICALS	Dermatologicals	[1] For the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable; [2] As an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma; [3] As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis; [4] For the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40kg, with eosinophilic esophagitis	For the treatment of adult patients with prurigo nodularis (PN)	9/28/2022
FIRDAPSE™ (AMIFAMPRIDINE PHOSPHATE) TABLETS / CATALYST PHARMAS	Antimyasthenic/cholinergic agents	Treatment of Lambert-Easton myasthenic syndrome (LEMS) in adults	Treatment of LEMS in adults and pediatric patients 6 years of age and older	9/29/2022

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DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	ADDITIONAL INFORMATION	IMPACT
NOV03 (PERFLUOROHEXYLOCTANE) EYE DROPS/ BAUSCH + LOMB CORPORATION AND NOVALIQ GMBH	9/6/2022	Signs and symptoms of dry eye disease (DED) associated with Meibomian gland dysfunction (MGD)	In July of this year Bausch + Lomb Corporation had submitted the NDA for NOV03. The FDA has announced that it has accepted the NDA and has assigned a Prescription Drug User Fee Act (PDUFA) action date of June 28, 2023. NDA accepted.	High
TP-03 (LOTILANER 0.25%) OPHTHALMIC SOLUTION / TARSUS PHARMACEUTICALS, INC.	9/7/2022	Treatment of *Demodex* blepharitis	TP-03 is a novel, investigational drug that designed to resolve the signs of *Demodex* blepharitis by targeting and eradicating the root cause of the disease – *Demodex* mite infestation. NDA submitted.	High
RITLECITINIB / PFIZER INC.	9/9/2022	Treatment of adults and adolescents 12 years of age and older with alopecia areata	Ritlecitinib is an investigational oral once daily treatment that is the first in a new class of oral highly selective kinase inhibitors that is a dual inhibitor of the TEC family of tyrosine kinases and of Janus kinase 3 (JAK3). The FDA is expected to make a decision in the second quarter of 2023. NDA submitted.	High
MOTIXAFORTIDE / BIOLINERX LTD.	9/12/2022	For use to mobilize hematopoietic stem cells (HSCs) from the marrow to peripheral blood for collection for autologous transplantation	Motixafortide may become a key component of a new standard of care for all multiple myeloma patients undergoing autologous stem cell transplantation. It has been granted orphan drug designation. The potential PDUFA date would be in Q2 2023 (under a priority review process, if applicable) or Q3 2023 (under a standard review process). NDA submitted.	High high

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DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	ADDITIONAL INFORMATION	IMPACT
TROFINETIDE / ACADIA PHARMACEUTICALS	9/12/2022	Treatment of Rett syndrome	Trofinetide is a novel synthetic analog of the amino-terminal tripeptide of IGF-1 designed to treat the core symptoms of Rett syndrome by potentially reducing neuroinflammation and supporting synaptic function. The FDA has granted a priority review and assigned a PDUFA action date of March 12th, 2023. NDA accepted.	High
REZAFUNGIN / CIDARA THERAPEUTICS	9/20/2022	Treatment of candidemia and invasive candidiasis	Rezafungin is a novel once-weekly echinocandin specifically designed to improve the mechanism of action of echinocandins to enhance its efficacy and safety potential for patients. The FDA has granted a priority review and assigned a PDUFA action date of March 22nd, 2023. NDA accepted.	Moderate
ROCTAVIAN™ (VALOCTOCOGENE ROXAPARVOVEC) / BIOMARIN PHARMACEUTICAL INC.	9/29/2022	Treatment of adults with severe hemophilia A	BioMarin Pharmaceutical Inc. resubmits NDA in response to the Complete Response letter issued by the FDA in August 2020. The FDA granted Regenerative Medicine Advanced Therapy (RMAT) designation to valoctocogene roxaparvovec in March 2021 in addition to Breakthrough Therapy and orphan drug designation. NDA resubmitted.	High high

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