OPTUMRx®

RxHighlights

September 2019

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Ferriprox® (deferiprone) 1000 mg tablet ApoPharma	Iron chelating agent	Treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate	August 5, 2019
Gvoke™ (glucagon) 0.5 mg/0.1 mL and 1 mg/0.2 mL single-dose pre-filled syringes and single-dose pre-filled HypoPen auto-injectors Xeris Pharmaceuticals	Glucagon analog	Treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above	September 15, 2019¥
Ibsrela® (tenapanor)* Ardelyx	Sodium-hydrogen exchanger-3 inhibitor	Treatment of irritable bowel syndrome with constipation in adults	TBD
Jynneos™ (smallpox and monkeypox vaccine, live, nonreplicating)* Bavarian Nordic	Vaccine	Prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection	TBD
Octagam® [immune globulin (human)] 30 gm/300 mL intravenous solution Octapharma USA	Immunoglobulin	Indicated in chronic immune thrombocytopenic purpura to rapidly raise platelet counts to control or prevent bleeding in adults	August 27, 2019

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Ozobax™ (baclofen) oral solution Metacel Pharmaceuticals	Gamma-aminobutyric acid agonist	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Ozobax may also be of some value in patients with spinal cord injuries and other spinal cord diseases.	TBD
Rybelsus® (semaglutide) tablets Novo Nordisk	Glucagon-like peptide-1 receptor agonist	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	September 22, 2019

*New molecular entity TBD: To be determined
¥Gvoke PFS launch date, Gvoke HypoPen to launch in 2020

New generics

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Amicar® (aminocaproic acid) Clover Pharmaceuticals	Amneal Pharmaceuticals†±	0.25 g/mL oral solution	Enhancing hemostasis when fibrinolysis contributes to bleeding	September 5, 2019
Emend® (fosaprepitant) Merck	Apotex†, Dr. Reddy's†, Novadoz/MSN Labs†, Mylan†Δ, Lupin†, Sungen†, Fresenius Kabi†, Baxter†, Be Pharmaceuticals†	115 mgΔ and 150 mg injection	Nausea and vomiting associated with emetogenic cancer chemotherapy	September 5, 2019¥
Orfadin® (nitisinone) Swedish Orphan Biovitrum	Novitum/Par†	2 mg, 5 mg, 10 mg, and 20 mg capsules	Treatment of hereditary tyrosinemia type 1	September 22, 2019

†A-rated generic manufacturer ±Granted 180 days of marketing exclusivity TBD: To be determined
¥Apotex, Baxter, Be Pharmaceuticals, Dr. Reddy's, Mylan, and Novadoz/MSN launch date; other manufacturers TBD
ΔMylan received FDA approval for a 115 mg injection product. Launch plans are pending.

New authorized brand alternatives

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Drug name Manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
NovoLog® (insulin aspart) Novo Nordisk	Novo Nordisk	10 mL vial/1,000 units 3 mL PenFill® (box of 5 pens)/1,500 units 3 mL FlexPen® (box of 5 pens)/1,500 units	To improve glycemic control in patients with diabetes mellitus	January 2, 2020
NovoLog® Mix (insulin aspart protamine/insulin aspart) Novo Nordisk	Novo Nordisk	10 mL vial/1,000 units 3 mL FlexPen® (box of 5 pens)/1,500 units	To improve glycemic control in patients with diabetes mellitus	January 2, 2020

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Aczone® (dapsone) Almirall	Expanded indication	Topical treatment of acne vulgaris in patients 9 years of age and older
Crysvita® (burosumab-twza) Ultragenyx, Kyowa Kirin	Expanded indication	Treatment of X-linked hypophosphatemia in patients 6 months of age and older
Darzalex® (daratumumab) Janssen	Expanded indication	In combination with Velcade® (bortezomib), Thalomid® (thalidomide), and dexamethasone, for the treatment of multiple myeloma in newly diagnosed patients who are eligible for autologous stem cell transplant

Delstrigo® (doravirine/lamivudine/tenofovir disoproxil fumarate) Merck	Expanded indication	A complete regimen for the treatment of human immunodeficiency virus (HIV)-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Delstrigo
Dysport® (abobotulinumtoxinA) Ispen Biopharmaceuticals	Expanded indication	Treatment of upper limb spasticity in patients 2 years of age and older, excluding spasticity caused by cerebral palsy
Erleada® (apalutamide) Janssen	New indication	Treatment of patients with metastatic castration-sensitive prostate cancer
Glucagon Fresenius Kabi	New indication	Treatment of severe hypoglycemia
Invokana® (canagliflozin) Janssen	New indication	To reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria > 300 mg/day
Lenvima® (lenvatinib) Eisai **Keytruda®** (pembrolizumab) Merck	New indication	Lenvima, used in combination with Keytruda, for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation
Mavyret® (glecaprevir/pibrentasvir) AbbVie	Label update	Eight week duration for the treatment of patients 12 years and older or weighing at least 45 kg who have chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection and compensated cirrhosis and have not been previously treated for HCV. This update shortens the treatment duration from 12 weeks to 8 weeks.
Nucala® (mepolizumab) GlaxoSmithKline	Expanded indication	Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype
Ofev® (nintedanib) Boehringer Ingelheim	New orphan indication	To slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease
Pifeltro® (doravirine) Merck	Expanded indication	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated

		with resistance to doravirine
Rituxan® (rituximab) Genentech	Expanded orphan indication	In combination with glucocorticoids, for the treatment of patients 2 years of age and older with Granulomatosis with Polyangiitis (Wegener's Granulomatosis) and Microscopic Polyangiitis
Teflaro® (ceftaroline fosamil) Allergan	Expanded indication	In adult and pediatric patients (at least 34 weeks gestational age and 12 days postnatal age) for the treatment of acute bacterial skin and skin structure infections caused by certain microorganisms

Drug safety news

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Drug name Manufacturer(s)	Description
Ranitidine	The FDA announced that some ranitidine medicines contain N-nitrosodimethylamine (NDMA), at low levels. NDMA is classified as a probable human carcinogen based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables. The FDA is not calling for individuals to stop taking ranitidine at this time; however, patients taking prescription ranitidine who wish to discontinue use should talk to their health care professional about other treatment options.
Ibrance® (palbociclib), **Kisqali®** (ribociclib), and **Verzenio®** (abemaciclib) Pfizer (Ibrance), Novartis (Kisqali), Eli Lilly (Verzenio)	The *Warnings and Precautions* sections of the Ibrance, Kisqali, and Verzenio drug labels were updated with information regarding interstitial lung disease and pneumonitis.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Calcilo XD® Abbott Nutrition	13.2 oz/375 g powder cans	Recall	Abbott Nutrition announced a voluntary, consumer-level recall of one lot of Calcilo XD powder cans due to an inconsistency in aroma and color in a small number of cans from this specific batch. Calcilo XD is used for nutrition support of infants with hypercalcemia, as may occur in infants with Williams syndrome, osteopetrosis, and primary neonatal hyperparathyroidism, and when a low-calcium, vitamin D-free formula is needed. Calcilo XD is used under medical supervision.
Capastat® Sulfate (capreomycin) Akorn	1 g, 10 mL vial	Shortage	The drug shortage of Akorn's Capastat Sulfate injection is ongoing. Capastat has been unavailable due to a delay in shipping. Akorn states that the estimated release date for product is unknown at this time. Capastat, used with other antituberculosis agents, is indicated for the treatment of pulmonary infections caused by capreomycin-susceptible strains of *Mycobacterium tuberculosis* when the primary agents have been ineffective or cannot be used because of toxicity or due to the presence of resistant tubercle bacilli.
Intron® A (interferon alfa-2b) Merck	Powder for injection: 10 million IU/vial, 18 million IU/vial, 50 million IU/vial Solution for injection: 25 million IU multi-dose vials	Discontinuation	Merck announced the discontinuation of Intron A. The discontinuation is not due to product quality, safety, or efficacy concerns. The single dose vials will be discontinued in 2022 and the multi-dose vials will be discontinued in 2021. Intron A is indicated for the treatment of hairy cell leukemia, malignant melanoma, follicular lymphoma, condylomata acuminate, AIDS-related Kaposi's sarcoma, chronic hepatitis C, and chronic hepatitis B

Losartan-containing products Torrent	Losartan: 50 mg and 100 mg tablets Losartan/HCTZ: 50 mg/12.5 mg and 100 mg/25 mg tablets	Recall	The FDA announced a consumer-level recall of several lots of Torrent's losartan and losartan/hydrochlorothiazide (HCTZ) tablets due to the detection of trace amounts of N-Methylnitrosobutyric acid (NMBA) in the active pharmaceutical ingredient manufactured by Hetero Labs. This recall is the fifth expansion to the original Torrent recall announced in January 3, 2019. Losartan and losartan/HCTZ tablets are used for the treatment of hypertension (HTN) and to reduce the risk of stroke in patients with HTN and left ventricular hypertrophy. Losartan tablets are also used for the treatment of diabetic nephropathy in patients with type 2 diabetes and a history of HTN.
Natpara® (parathyroid hormone) Takeda	25 mcg, 50 mcg, 75 mcg, 100 mcg injection	Recall	Takeda announced a voluntary patient-level recall of all doses of Natpara injection due to a potential issue related to rubber particulates originating from the rubber septum of the Natpara cartridge. Natpara is indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.
Milk of Magnesia Plastikon	2400 mg/30 mL oral suspension	Recall	Plastikon announced a voluntary, patient-level recall of two lots of milk of magnesia 2400 mg/30 mL oral suspension because these lots did not meet Plastikon's in-house microbiological specification for total aerobic microbial count. Milk of magnesia is indicated for the occasional relief of constipation.
Pegintron® (peginterferon alfa-2b) Merck	50 mcg/0.5mL vial	Discontinuation	Merck announced the discontinuation of Pegintron. The discontinuation is not due to product quality, safety, or efficacy concerns. The product will be discontinued on or near May 2021. Pegintron is indicated for the treatment of chronic hepatitis C in patients with compensated liver disease.

Ranitidine Apotex	75 mg and 150 mg tablets	Recall	The FDA alerted healthcare providers and patients to a voluntary, retail level recall of Apotex's over-the-counter (OTC) ranitidine tablets labeled by Walgreens, Walmart, and Rite-Aid due to potential contamination with low levels of N-Nitrosodimethylamine (NDMA). OTC ranitidine is approved to prevent and relieve heartburn associated with acid ingestion and sour stomach.
Ranitidine Sandoz	150 mg and 300 mg capsules	Recall	The FDA announced a consumer-level recall of several lots of Sandoz's ranitidine capsules because of contamination with NDMA above levels established by the FDA in batches of Sandoz's ranitidine capsules. Ranitidine is indicated for the treatment of duodenal ulcer, benign gastric ulcer, reflux esophagitis, post-operative peptic ulcer, Zollinger-Ellison Syndrome, and other conditions where reduction of gastric secretion and acid output is desirable.

Key guideline/literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia – Version 2.2020	*NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas – Version 5.2019	*NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer – Version 3.2019	*NCCN Clinical Practice Guidelines in Oncology: Breast Cancer*. September 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers – Version 2.2019	*NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer – Version 5.2019	*NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia – Version 2.2020	*NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer – Version 3.2019	*NCCN Clinical Practice Guidelines in Oncology: Colon Cancer*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers – Version 3.2019	*NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma – Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms – Version 3.2019	*NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer – Version 2.2019	*NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer*. September 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer – Version 3.2019	*NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma – Version 4.2019	*NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma – Version 2.2019	*NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma*. September 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms – Version 4.2019	*NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms*. September 2019

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