OPTUMRx®

RxHighlights

November 2020

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Bronchitol® (mannitol)† Chiesi	Osmotic gradient enhancer; mucus clearance enhancer	Add-on maintenance therapy to improve pulmonary function in adult patients 18 years and older with cystic fibrosis	March 2021
Danyelza® (naxitamab-gqgk)†* Y-mAbs Therapeutics	GD2 antagonist	In combination with granulocyte-macrophage colony-stimulating factor, for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy	November 30, 2020
Imcivree™ (setmelanotide)†* Rhythm	Melanocortin 4 receptor agonist	Chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in *POMC, PCSK1, or LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance	1st quarter 2021
Oxlumo® (lumasiran)†* Alnylam	HAO1-directed small interfering ribonucleic acid (siRNA)	Treatment of primary hyperoxaluria type 1 to lower urinary oxalate levels in pediatric and adult patients	November 25, 2020

Sesquient™ (fosphenytoin sodium) Sedor	Anticonvulsant	Treatment of generalized tonic-clonic status epilepticus in adult patients; prevention and treatment of seizures occurring during neurosurgery in adult patients; short-term substitution for oral phenytoin in patients 2 years of age and older	TBD
Sutab® (sodium sulfate/magnesium sulfate/potassium chloride) Sebela, Braintree Laboratories	Osmotic laxative	Cleansing of the colon as a preparation for colonoscopy in adults	January 1, 2021
Ultomiris® (ravulizumab-cwvz) 300 mg/3 mL (100 mg/mL) single-dose vial Alexion	C5 complement inhibitor	Treatment of adult patients with paroxysmal nocturnal hemoglobinuria and for the treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy	October 13, 2020
Zokinvy™ (lonafarnib)†* Eiger BioPharmaceuticals	Farnesyltransferase inhibitor	In patients 12 months of age and older with a body surface area of 0.39 m^2 and above to reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome; Treatment of processing-deficient Progeroid Laminopathies with either: heterozygous *LMNA* mutation with progerin-like protein accumulation or homozygous or compound heterozygous *ZMPSTE24* mutations	TBD

*New molecular entity; †Orphan Drug; TBD: To be determined

New generics

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Alinia® (nitazoxanide) Romark	Rising†	500 mg tablets	Diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum*	November 30, 2020

Banzel® (rufinamide) Eisai	Bionpharma†, Hikma†	40 mg/mL oral suspension	Seizures associated with Lennox-Gastaut Syndrome	November 4, 2020±
Taytulla® (ethinyl estradiol/norethindrone/ferrous fumarate) Allergan	Xiromed†¥	ethinyl estradiol/ norethindrone: 20 mg/1 mg (24 caps) and ferrous fumarate: 75 mg (4 caps)	Prevention of pregnancy	November 9, 2020
Tirosint® (levothyroxine) IBSA Institut Biochemique	Teva†	75 mcg and150 mcg capsules	Hypothyroidism; and as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer	TBD
Vascepa® (icosapent ethyl) Amarin	Dr. Reddy's†, Hikma†, Teva†€	500 mg and 1 gm capsules	Adjunct to diet to reduce triglyceride levels in adults with severe hypertriglyceridemia	November 5, 2020§

†A-rated generic manufacturer; TBD: to be determined
¥Branded generic marketed as Gemmily™; ±Launch for Hikma, Bionpharma TBD; §Launch for Hikma, Dr. Reddy's and Teva TBD; €Teva received approval for 500 mg and 1 gm caps

New authorized brand alternatives

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Tirosint® (levothyroxine) IBSA Institut Biochemique	Lannett	13 mcg, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, and 200 mcg capsules	Hypothyroidism; and as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer	November 3, 2020

Taytulla® (ethinyl estradiol/norethindrone/ferrous fumarate) Allergan	Greenstone	20 mg/1 mg (24 caps) and 75 mg (4 caps)	Prevention of pregnancy	November 11, 2020

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Brilinta® (ticagrelor) AstraZeneca	New indication	To reduce the risk of stroke in patients with acute ischemic stroke or high-risk transient ischemic attack
Keytruda® (pembrolizumab) Merck	New indication	In combination with chemotherapy, for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumors express PD-L1 as determined by an FDA-approved test
Olumiant® (baricitinib) Eli Lilly	Emergency use authorization approval	Treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation
Selzentry® (maraviroc) ViiV Healthcare	Expanded indication	In combination with other antiretroviral agents for the treatment of only CCR5-tropic human immunodeficiency virus type 1 infection in adult and pediatric patients weighing at least 2 kg
Totect® (dexrazoxane) Clinigen	New indication	Reducing the incidence and severity of cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300 mg/m^2 and who will continue to receive doxorubicin therapy to maintain tumor control
Vimpat® (lacosamide) UCB	New indication	Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older

Xofluza® (baloxavir marboxil) Genentech	New indication, new formulation approval	Post-exposure prophylaxis of influenza in persons 12 years of age and older following contact with an individual who has influenza The FDA approved a new oral suspension formulation (40 mg/20 mL) of Xofluza.

Drug safety news

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Drug name Manufacturer(s)	Description
Forteo® (teriparatide) Eli Lilly	The FDA approved several updates to Eli Lilly's Forteo drug label, including: removal of the boxed warning regarding osteosarcoma; modification of the dosing and administration section to allow for longer duration of treatment in patients who remain at or return to having a high risk for fracture; and addition of the risk of cutaneous calcification including calciphylaxis to the existing warning regarding hypercalcemia and hypercalcemic disorders.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Bydureon® (exenatide) AstraZeneca	Single-dose pen containing 2 mg of exenatide	Discontinuation	AstraZeneca announced that Bydureon Pen will be discontinued as of March 2021 due to business reasons. The discontinuation is not due to safety or efficacy issues, product quality or manufacturing concerns. Bydureon BCise will continue to be available. When patients are switched from Bydureon to Bydureon BCise, a new prescription is needed. Bydureon Pen is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Chlorhexidine gluconate Lohxa	0.12% oral rinse	Recall	Lohxa announced a voluntary, consumer level recall of several lots of chlorhexidine gluconate, labeled with expiration dates of 1/31/21 – 3/31/21, due to contamination with *Burkholderia lata*. Chlorhexidine gluconate is indicated for the treatment of gingivitis.
Metformin extended-release Nostrum	500 mg ER and 750 mg ER tablets	Recall	Nostrum announced a voluntary, consumer level recall of some lots of metformin due to contamination with n-nitrosodimethylamine (NDMA) above the acceptable daily intake limit of 96 ng/day. Metformin is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients ≥ 10 years of age with type 2 diabetes mellitus.
Picato® (ingenol mebutate) LEO Pharma	0.015% and 0.05% gel	Discontinuation	LEO Pharma announced the permanent discontinuation of Picato gel due to business reasons. The discontinuation is not due to any safety, efficacy or quality issues. The phase-out is expected to be completed by year-end 2020. Picato is approved for the topical treatment of actinic keratosis.

Key guideline/literature updates

Topic	Reference
American Society of Hematology - Management of Venous Thromboembolism: Treatment of Deep Vein Thrombosis and Pulmonary Embolism	*Blood Advances*. October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia - Version 2.2021	*NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia*. November 2020

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer - Version 1.2021	*NCCN Clinical Practice Guidelines in Oncology: Bone Cancer*. November 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers - Version 1.2021	*NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers*. November 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous - Version 1.2021	*NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous*. November 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 1.2021	*NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer*. November 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary - Version 1.2021	*NCCN Clinical Practice Guidelines in Oncology: Occult Primary*. November 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer - Version 3.2020	*NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer*. November 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Testicular Cancer - Version 1.2021	*NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer*. November 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 2.2021	*NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic*. November 2020

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