OPTUMRx®

RxHighlights

August 2021

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Comirnaty® (COVID-19 vaccine, mRNA) Pfizer, BioNTech	Vaccine	For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older	TBD
Korsuva™ (difelikefalin)* Vifor Pharma, Cara Therapeutics	Kappa opioid receptor agonist	Treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis	First Quarter 2022
Nexviazyme® (avalglucosidase alfa-ngpt)†* Sanofi	Enzyme replacement therapy	Treatment of patients 1 year of age and older with late-onset Pompe disease [lysosomal acid alpha-glucosidase deficiency]	August 10, 2021
Saphnelo® (anifrolumab-fnia)* AstraZeneca	Interferon receptor antagonist	Treatment of adult patients with moderate to severe systemic lupus erythematosus, who are receiving standard therapy	August 04, 2021
Skytrofa® (lonapegsomatropin-tcgd)†* Ascendis Pharma	Growth hormone prodrug	Treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone	TBD
Ticovac™ (tick-borne encephalitis vaccine) Pfizer	Vaccine	For active immunization to prevent tick-borne encephalitis. Ticovac is approved for use in individuals 1 year of age and older	TBD
Welireg™ (belzutifan)†* Merck	Hypoxia-inducible factor-2 alpha inhibitor	Treatment of adult patients with von Hippel-Lindau disease who require therapy for associated renal cell carcinoma, central nervous	August 30, 2021

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
		system hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery	

*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
Duexis® (ibuprofen/famotidine) Horizon	Alkem†	800 mg/26.6 mg tablets	For the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers	August 4, 2021
Durezol® (difluprednate) Alcon	Cipla†	0.05% ophthalmic emulsion	Inflammation and pain associated with ocular surgery; endogenous anterior uveitis	TBD
Epaned® (enalapril) Azurity	Bionpharma†	1 mg/ mL oral solution	Hypertension	August 16, 2021
Sutent® (sunitinib) Pfizer	Sun†	12.5 mg, 25 mg, 37.5 mg, and 50 mg capsules	Gastrointestinal stromal tumor, advanced renal cell carcinoma, adjuvant treatment of renal cell carcinoma, and advanced pancreatic neuroendocrine tumors	August 16, 2021

†A-rated generic manufacturer; TBD: to be determined

Indications/Label updates

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Drug name Manufacturer(s)	Type	Description
Briviact® (brivaracetam) UCB	Expanded indication	Treatment of partial-onset seizures in patients 1 month of age and older.
COVID-19 vaccines Pfizer-BioNTech, Moderna	Emergency use authorization (EUA) update	The FDA approved an amendment to the EUAs for both the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine to allow for the use of an additional dose in certain immunocompromised individuals. The authorizations for these vaccines have been amended to allow for an additional, or third, dose to be administered at least 28 days following the two-dose regimen of the same vaccine to individuals 18 years of age or older (ages 12 or older for Pfizer-BioNTech) who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.
Evomela® (melphalan) Acrotech Biopharma	Indication withdrawal	The FDA approved the voluntary removal of Acrotech Biopharma's Evomela indication for palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate
Istodax® (romidepsin) Bristol-Myers Squibb	Indication withdrawal	Bristol-Myers Squibb is voluntarily withdrawing the indication for monotherapy for the treatment of peripheral T-cell lymphoma in adult patients who have received at least one prior therapy because a trial did not need the primary efficacy endpoint of progression free survival.
Jardiance® (empagliflozin) Boehringer Ingelheim, Eli Lilly	New indication	To reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction
Jemperli (dostarlimab-gxly) GlaxoSmithKline	New indication	Treatment of adult patients with mismatch repair deficient recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options
Keytruda® (pembrolizumab) Merck	Updated indication	Treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for any platinum-containing chemotherapy
Keytruda® (pembrolizumab) and **Lenvima®** (lenvatinib) Merck, Eisai	Expanded indication	Keytruda, in combination with Lenvima, for the first-line treatment of adult patients with advanced renal cell carcinoma

Drug name Manufacturer(s)	Type	Description
Lexette® (halobetasol propionate) Mayne Pharma	Expanded indication	Topical treatment of plaque psoriasis in patients 12 years of age and older
Mirena® (levonorgestrel-releasing intrauterine system) Bayer	Expanded indication	Prevention of pregnancy for up to 7 years; replace after the end of the seventh year
Opdivo® (nivolumab) Bristol Myers Squibb	Expanded indication	Adjuvant treatment of patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC
Tecentriq® (atezolizumab) Roche	Indication withdrawal	Roche announced the voluntary withdrawal of the Tecentriq indication for use in combination with paclitaxel protein-bound, for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells of any intensity covering ≥ 1% of the tumor area), as determined by an FDA-approved test
Tibsovo® (ivosidenib) Servier Pharmaceuticals	New indication	Treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 mutation as detected by an FDA-approved test
Xarelto® (rivaroxaban) Janssen	Expanded indication	In combination with aspirin, to reduce the risk of major thrombotic vascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in patients with peripheral artery disease (PAD), including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD
Xywav® (calcium/magnesium/potassium/sodium oxybates) Jazz Pharmaceuticals	New indication	Treatment of idiopathic hypersomnia in adults

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Atovaquone KVK Tech	750 mg/5 mL oral suspension	Recall	KVK Tech announced a voluntary, consumer-level recall of two lots of atovaquone oral suspension due to prolonged exposure to extremely cold weather during shipment. Atovaquone is indicated for the prevention and acute treatment of *Pneumocystis jiroveci* in patients who cannot tolerate trimethoprim-sulfamethoxazole.
Chantix® (varenicline) Pfizer	0.5 mg and 1 mg tablets	Recall	Pfizer announced an expansion of the voluntary consumer-level recall of Chantix tablets to include four additional lots due to the presence of a nitrosamine, N-nitroso-varenicline, above the Pfizer established acceptable daily intake level. Chantix is a treatment to help patients quit smoking.
Gamunex® -C (immune globulin [human]) Grifols Therapeutics	10% injection	Withdrawal	Grifols Therapeutics announced a voluntary, consumer-level withdrawal of several lots of Gamunex-C (immune globulin [human]) injection due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant. Gamunex-C is indicated for the treatment of primary humoral immunodeficiency in patients two years of age and older; idiopathic thrombocytopenic purpura in adults and children; and chronic inflammatory demyelinating polyneuropathy in adults.
Lidocaine topical solution Teligent Pharma	4% topical solution	Recall	Teligent Pharma announced a voluntary, patient-level recall of one lot of lidocaine topical solution 4% because testing has found it to be super potent based on an out of specification result obtained at the 18-month stability timepoint. Lidocaine topical solution is indicated for the production of topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract.

Key guideline/Literature updates

Topic	Reference
American Society of Colon and Rectal Surgeons - Management of *Clostridioides difficile* Infection	*Diseases of the Colon and Rectum*. – June 2021
Centers for Disease Control and Prevention - Antimicrobial Treatment and Prophylaxis of Plague	*Morbidity and Mortality Weekly Report*. – July 2021
Centers for Disease Control and Prevention - Sexually Transmitted Infections	*Morbidity and Mortality Weekly Report*. – July 2021
U.S. Department of Health and Human Services – Join Statement on COVID-19 Booster Doses	*Joint Statement from HHS and Medical Experts*. August 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia*. August 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 4.2021	*NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers*. August 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma*. August 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms - Version 2.2021	*NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms*. August 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors - Version 3.2021	*NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors*. August 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer*. August 2021

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer - Version 2.2021	*NCCN Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer*. August 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic*. August 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease - Version 2.2021	*NCCN Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease*. August 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship - Version 3.2021	*NCCN Clinical Practice Guidelines in Oncology: Survivorship*. August 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology*. August 2021

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