OPTUMRx®

RxHighlights

October 2021

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Rethymic® (allogeneic processed thymus tissue-agdc)†* Enzyvant	Tissue-based therapy	For immune reconstitution in pediatric patients with congenital athymia	October 28, 2021
Scemblix® (asciminib) †* Novartis	Allosteric Bcr-Abl inhibitor	Treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs). This indication is approved under accelerated approval based on major molecular response (MMR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).; Ph+ CML in CP with the T315I mutation	November 3, 2021
Seglentis® (celecoxib/tramadol) Esteve Pharmaceuticals	Non-steroid anti-inflammatory drug/opioid	Management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate	TBD
Sertraline capsules Almatica	Selective serotonin reuptake inhibitor	Treatment of major depressive disorder in adults and treatment of obsessive compulsive disorder in adults and pediatric patients 6 years and older	October 4, 2021
Susvimo™ (ranibizumab) Genentech	Anti-vascular endothelial growth factor	Treatment of patients with neovascular age-related macular degeneration who have previously responded to a least two intravitreal injections of a vascular endothelial growth factor inhibitor medication	October 31, 2021

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Tavneos™ (avacopan)†* ChemoCentryx	C5a receptor antagonist	Adjunctive treatment of adult patients with severe active antineutrophil cytoplasmic autoantibody-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis]) in combination with standard therapy including glucocorticoids	October 14, 2021
Tyrvaya™ (varenicline) nasal spray Oyster Point Pharma	Nicotinic acetylcholine receptor agonist	Treatment of the signs and symptoms of dry eye disease	October 21, 2021
Vuity™ (pilocarpine) Allergan, an AbbVie company	Cholinergic muscarinic receptor agonist	Treatment of presbyopia in adults	TBD
Xipere® (triamcinolone acetonide) Bausch + Lomb, Clearside Biomedical	Corticosteroid	Treatment of macular edema associated with uveitis	First quarter of 2022
Zimhi™ (naloxone) Adamis Pharmaceuticals	Opioid antagonist	In adults and pediatric patients, for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression	First quarter of 2022

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

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New biosimilars

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Cyltezo® (adalimumab-adbm)± Boehringer Ingelheim	Tumor necrosis factor	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis	July 1, 2023

±Interchangeable biosimilar to Humira (adalimumab)

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New generics

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Afinitor Disperz® (everolimus) Novartis	Mylan/Viatris†	2 mg, 3 mg, and 5 mg tablets for oral suspension	Tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma and TSC-associated partial-onset seizures	October 1, 2021
Afinitor® (everolimus) Novartis	Breckenridge†, Biocon†	10 mg tablets	Breast cancer; progressive neuroendocrine tumors of pancreatic, lung, and gastrointestinal origin; renal cell carcinoma; TSC	October 1, 2021

†A-rated generic manufacturer

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New authorized brand alternatives

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Antara® (fenofibrate) Lupin	Lupin	30 mg and 90 mg capsules	Primary hypercholesterolemia, mixed dyslipidemia, and severe hypertriglyceridemia	October 28, 2021

Indications/Label updates

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Drug name Manufacturer(s)	Type	Description
AZD7442 (tixagevimab/cilgavimab) AstraZeneca	Emergency use authorization (EUA) submission	AstraZeneca announced it had submitted an EUA request for AZD7442 for pre-exposure prophylaxis of symptomatic COVID-19 in people who aren't able to mount a protective response following vaccination and continue to be at risk of developing COVID-19
Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide) Gilead	Expanded indication, new strength	Complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 14 kg who have no antiretroviral treatment history or 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 Biktarvy A new low dose strength of Biktarvy tablets (30 mg of bictegravir, 120 mg of emtricitabine, and 15 mg of tenofovir alafenamide) was also approved.
COVID-19 Vaccines Moderna, Janssen, Pfizer	EUA amendment	The FDA has amended the EUAs for Pfizer, Moderna and Janssen's COVID-19 vaccines to allow for a single booster dose to be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.
Janssen-COVID-19 Vaccine Janssen	EUA amendment	The FDA has amended the EUA for the Janssen COVID-19 vaccine to allow for use of a single booster dose of Janssen COVID-19 vaccine to be administered at least 2 months after primary vaccination with the Janssen COVID-19 vaccine, to individuals 18 years of age and older.
Moderna-COVID-19 Vaccine Moderna	EUA amendment	The FDA has amended the EUA for the Moderna COVID-19 vaccine to allow for use of a single booster dose to be administered at least six months after completion of the primary series. The eligible population includes: individuals ≥ 65 years of age; individuals 18 through 64 years of age at high risk of severe COVID-19; and individuals 18 through 64 years of age with frequent institutional or occupational exposure to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
Pfizer/BioNTech COVID-19 Vaccine Pfizer/BioNTech	EUA expansion	The FDA announced an expanded EUA for the Pfizer/BioNTech COVID-19 vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 5 – 11 years of age
Dextenza® (dexamethasone ophthalmic insert)	New indication	Treatment of ocular itching associated with allergic conjunctivitis

Drug name Manufacturer(s)	Type	Description
Ocular Therapeutix		
Dupixent® (dupilumab) Sanofi and Regeneron	Expanded indication	An add-on maintenance treatment of patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma
Flucelvax® Quadrivalent (influenza vaccine) Seqirus	Expanded indication	For active immunization for the prevention of influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. Flucelvax Quadrivalent is approved for use in persons 6 months of age and older
Keytruda® (pembrolizumab) Merck	Expanded indication	In combination with chemotherapy, with or without bevacizumab, for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 as determined by an FDA-approved test
Molnupiravir Merck	EUA submission	Merck announced the submission of an application for EUA to the FDA for molnupiravir, an oral treatment for COVID-19. Molnupiravir is intended for the treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization.
Tecartus® (brexucabtagene autoleucel) Gilead	New indication	Treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia
Tecentriq® (atezolizumab) Roche	Expanded indication	As a single-agent, as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II to IIIA non-small cell lung cancer whose tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test
Verzenio® (abemaciclib) Eli Lilly	New indication, expanded indication	In combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor positive, human epidermal growth factor receptor 2-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score ≥ 20% as determined by an FDA approved test
Vimpat® (lacosamide) UCB	Expanded indication	Treatment of partial-onset seizures in patients 1 month of age and older

Drug recalls/Withdrawals/Shortages/Discontinuations

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Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Cubicin® (daptomycin) Merck	500 mg injection	Recall	The FDA announced a voluntary, user-level recall of one lot of Cubicin because of a customer complaint reporting that a piece of glass was found in a vial of Cubicin after reconstitution. Cubicin is indicated for the treatment of complicated skin and skin structure infections and for *Staphylococcus aureus* bloodstream infections.
Hizentra® [immune globulin subcutaneous (human)] CSL Behring	20% liquid	Withdrawal	CSL Behring announced a patient-level withdrawal of one lot of Hizentra due to an increased frequency of reports of injection-site reactions and local hypersensitivity-type of events after administration. Hizentra is indicated for the treatment of primary immunodeficiency and for maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy.
Irbesartan and **irbesartan/hydrochlorothiazide (HCTZ)** Lupin	irbesartan: 75 mg, 150 mg, and 300 mg tablets irbesartan/HCTZ: 150 mg/12.5 mg and 300 mg/12.5 mg	Recall	Lupin announced a consumer level recall of 15 lots of irbesartan tablets and 32 lots of irbesartan/HCTZ tablets because certain active pharmaceutical ingredient batches were above the specification limit for N-nitrosoirbesartan impurity. Irbesartan and irbesartan/HCTZ tablets are indicated for the treatment of hypertension (HTN). Irbesartan is also indicated for the treatment of diabetic nephropathy in patients with type 2 diabetes and HTN, an elevated serum creatinine, and proteinuria.
Lidocaine Teligent Pharma	4% topical solution	Recall	Teligent announced a voluntary, patient-level recall of five lots 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.
Lotrimin® AF and **Tinactin®** spray products	Various products	Recall	Bayer announced a voluntary, consumer-level recall of all unexpired Lotrimin Anti-Fungal and Tinactin over-the-counter spray products with

Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Bayer			lot numbers beginning with TN, CV or NAA, distributed between September 2018 to September 2021, due to the presence of benzene in some samples of the products.
Methocarbamol Bryant Ranch Prepack	500 mg tablets	Recall	The FDA announced a voluntary, consumer-level recall of methocarbamol 500 mg tablets because the bottles labeled as methocarbamol 500 mg tablets have been found to contain methocarbamol 750 mg tablets. Methocarbamol is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.
MiniMed™ insulin pumps Medtronic	MiniMed 600 Series insulin pumps (model 630G and model 670G)	Recall	The FDA announced an expansion to the voluntary, consumer-level recall of Medtronic's MiniMed 600 Series insulin pumps to replace any pump that has a clear retainer ring with one that has the updated black retainer ring.
Pepaxto® (melphalan flufenamide) Oncopeptides	20 mg/vial injection	Withdrawal	Oncopeptides announced the withdrawal of Pepaxto from the U.S. market following a clinical trial that demonstrated an overall survival in the intention to treat population with a hazard ratio of 1.104. In July 2021, the FDA announced that this study evaluating Pepaxto with dexamethasone to treat patients with multiple myeloma showed an increased risk of death.

Key guideline/Literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 5.2021	*NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer*. October 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer - Version 2.2022	*NCCN Clinical Practice Guidelines in Oncology: Bone Cancer*. October 2021

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer*. October 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 3.2022	*NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma*. October 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 7.2021	*NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer*. October 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma - Version 3.2021	*NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma*. October 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Lung Cancer Screening - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening*. October 2021

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