OPTUMRx®

RxHighlights

September 2021

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Exkivity™ (mobocertinib)†* Takeda	Tyrosine kinase inhibitor	Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy	September 19, 2021
Invega Hafyera™ (paliperidone palmitate) Janssen	Atypical antipsychotic	Treatment of schizophrenia in adults after they have been adequately treated with: a once-a-month paliperidone palmitate extended-release injectable suspension for at least four months; or an every-three-month paliperidone palmitate extended-release injectable suspension for at least one three-month cycle	September 9, 2021
Livmarli™ (maralixibat)†* Mirum	Apical sodium-dependent bile acid transporter inhibitor	Treatment of cholestatic pruritus in patients with Alagille syndrome 1 year of age and older	September 30, 2021
Loreev XR® (lorazepam) extended-release capsules Almatica Pharma	Benzodiazepine	Treatment of anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets	September 7, 2021
Opdivo® (nivolumab) 120 mg/12 mL injection Bristol Myers Squibb	Programmed death receptor-1-blocking antibody	Treatment of melanoma; non-small cell lung cancer; malignant pleural mesothelioma; renal cell carcinoma; classical Hodgkin lymphoma; squamous cell carcinoma of the head and neck. Urothelial carcinoma; colorectal cancer; hepatocellular carcinoma; esophageal cancer; gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma	September 1, 2021
Qulipta™ (atogepant)*	Calcitonin gene-related peptide receptor antagonist	Preventive treatment of episodic migraine in adults	October 4, 2021

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
AbbVie			
Tivdak™ (tisotumab vedotin-tftv)* Seagen, Genmab	Tissue factor-directed antibody and microtubule inhibitor conjugate	Treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy	September 22, 2021
Trudhesa™ (dihydroergotamine mesylate) Impel NeuroPharma	Ergot derivative	Acute treatment of migraine with or without aura in adults	September 20, 2021

*New molecular entity; † Orphan drug

New biosimilars

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Byooviz™ (ranibizumab-nuna) Samsung Bioepsis, Biogen	Anti-VEGF (vascular endothelial growth factor) antibody fragment	Neovascular (wet) age-related macular degeneration; macular edema following retinal vein occlusion; and myopic choroidal neovascularization	June 2022

New generics

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Chantix® (varenicline) Pfizer	Par†	0.5 mg and 1 mg tablets	Smoking cessation	September 22, 2021
Bystolic® (nebivolol) Allergan	Camber/Hetero†, Torrent†, Ascend† and ANI Pharmaceuticals†	2.5 mg, 5 mg, 10 mg, and 20 mg tablets	Hypertension	September 17, 2021
Paxil® (paroxetine hydrochloride) Apotex	Novitium†	10 mg/5 mL oral suspension	Major depressive disorder, obsessive compulsive disorder, panic disorder, social anxiety disorder, generalized anxiety disorder, and posttraumatic stress disorder	September 10, 2021

†A-rated generic manufacturer

Indications/Label updates

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Drug name Manufacturer(s)	Type	Description
Pfizer-BioNTech COVID-19 vaccine Pfizer	Emergency use authorization (EUA) amendment	The FDA amended the EUA for the Pfizer-BioNTech COVID-19 vaccine to allow for use of a single booster dose administered at least six months after completion of the primary series. The eligible population includes: Individuals 65 years of age and older; Individuals 18 through 64 years of age at high risk of severe COVID-19; and Individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.
Bamlanivimab / etesevimab Eli Lilly	EUA expansion	For post-exposure prophylaxis of COVID-19 in adult and pediatric individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are: not fully vaccinated or who are not expected to mount an adequate immune response to complete severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination; and have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention; or who are at high risk of exposure to an

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		individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting
Brukinsa® (zanubrutinib) BeiGene	New indication	Treatment of adults with relapsed or refractory marginal zone lymphoma who have received at least one anti-CD20-based regimen
	New orphan indication	Treatment of adults with Waldenström's macroglobulinemia
Cabometyx® (cabozantinib) Exelixis	New indication	Treatment of adult and pediatric patients ≥ 12 years of age with locally advanced or metastatic differentiated thyroid cancer that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible
Erbitux® (cetuximab) Eli Lilly	New indication	In combination with Braftovi® (encorafenib), for the treatment of adults with metastatic colorectal cancer with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy
Jakafi® (ruxolitinib) Incyte	New indication	Treatment of chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients ≥ 12 years of age
Repatha® (evolocumab) Amgen	New indication	As an adjunct to diet and other low-density lipoprotein-cholesterol (LDL-C)-lowering therapies in pediatric patients ≥ 10 years of age with heterozygous familial hypercholesterolemia, to reduce LDL-C
	Expanded indication	As an adjunct to other LDL-C-lowering therapies in adults and pediatric patients ≥ 10 years of age with homozygous familial hypercholesterolemia, to reduce LDL-C
Tasigna® (nilotinib) Novartis	Expanded indication	Treatment of patients ≥ 1 year of age with chronic phase and accelerated phase Philadelphia chromosome positive chronic myeloid leukemia with resistance or intolerance to prior tyrosine-kinase inhibitor therapy

Drug safety news / Drug updates

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Drug name Manufacturer(s)	Description
COVID-19 Vaccine Update for Children Pfizer	Pfizer announced top-line results from a Phase 2/3 trial evaluating the Comirnaty® vaccine in children ages 5 to 11 years old. This is the first COVID-19 vaccine data available in children younger than 12 years. Pfizer plans to share this information with the FDA to be included in the EUA for Comirnaty. Before COVID-19 vaccines can be given to children < 12 years old, the FDA must authorize this use and the CDC's ACIP panel will review the evidence and issue recommendations. The FDA has not yet revised the EUA for use in children younger than 12 years of age.
COVID-19 Vaccine Booster Janssen	Janssen (Johnson & Johnson) announced new data on their COVID-19 vaccine showing that protection against COVID-19 increases when a booster shot of the vaccine is administered following the initial 1-dose regimen. The safety profile of the vaccine remained consistent and was generally well-tolerated when administered as a booster. The data has been shared with the FDA for review and may ultimately inform a revision of the EUA for the Janssen COVID-19 vaccine. To date, timing for an EUA change has not been shared.
Oral Janus kinase (JAK) inhibitors Xeljanz®/XR (tofacitinib), Olumiant® (baricitinib), and Rinvoq® (upadacitinib)	The FDA announced that after review of a large, randomized safety clinical trial, there is an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with Xeljanz, Xeljanz XR. The FDA believes the other JAK inhibitors, Olumiant and Rinvoq, have similar risks because they share the same mechanism of action as Xeljanz.

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Aminosyn® II (an amino acid injection, sulfite-free) ICU Medical	15% injection	Recall	ICU Medical announced a voluntary, user level recall of one lot of Aminosyn II 15% because of the presence of visible particulate matter. Aminosyn II is indicated as a source of nitrogen in the nutritional support of patients.
Chantix® (varenicline) Pfizer	0.5 mg and 1 mg tablets	Recall	Pfizer announced a voluntary consumer-level recall of all lots of Chantix tablets due to the presence of a nitrosamine, N-nitroso-varenicline, at or above the FDA interim acceptable daily intake limit. Chantix is a treatment to help patients quit smoking.
Firvanq® (vancomycin for oral solution) Azurity	50 mg/mL kit	Recall	Azurity announced a voluntary, patient-level recall of one lot of Firvanq because some products in the affected lot have been found to incorrectly contain a First Omeprazole diluent instead of the Firvanq diluent bottle. Firvanq is indicated for the treatment of *Clostridium difficile*-associated diarrhea and for the treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains).
Glucagon® Emergency Kit Eli Lilly	1 mg per vial; diluent for glucagon, 1 mL syringe	Recall	Eli Lilly announced a voluntary, patient-level recall of one lot of Glucagon Emergency Kit for Low Blood Sugar because of a product complaint reporting that the vial of glucagon was in liquid form instead of the powder form. Glucagon Emergency Kit is used as an anti-hypoglycemic agent and a gastrointestinal motility inhibitor for the treatment of severe hypoglycemia in patients with diabetes.
Glycopyrrolate Meitheal	4 mg per 20 mL injection	Recall	Meitheal announced a voluntary, user level recall of four lots of glycopyrrolate injection because of an out of specification result observed for benzaldehyde content. Glycopyrrolate injection is indicated for use as a preoperative antimuscarinic and for use as adjunctive therapy for the treatment of

Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
			peptic ulcer when rapid anticholinergic effect is desired or when oral medication is not tolerated.
Ruzurgi® (amifampridine) Jacobus	10 mg tablets	Recall	Jacobus announced a voluntary, consumer level recall of three lots of Ruzurgi because the tablets have been found to be contaminated with yeast, mold, and aerobic bacteria based on laboratory test results. Ruzurgi is approved for the treatment of Lambert-Eaton myasthenic syndrome.

Key guideline/Literature updates

Topic	Reference
American Society of Pain and Neuroscience – Interventional Management of Cancer-Associated Pain	*Journal of Pain Research*. July 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 5.2021	*NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas*. September 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 8.2021	*NCCN Clinical Practice Guidelines in Oncology: Breast Cancer*. September 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 5.2021	*NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers*. September 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation - Version 5.2021	*NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation*. September 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities - Version 4.2021	*NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities*. September 2021

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