OPTUMRx®

RxHighlights

July 2021

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Bylvay™ (odevixibat)†* Albireo Pharma	Ileal bile acid transport inhibitor	Treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis	July 27, 2021
Fexinidazole†* Sanofi	Nitroimidazole antimicrobial	Treatment of both the first-stage (hemolymphatic) and second-stage (meningoencephalitic) human African trypanosomiasis due to *Trypanosoma brucei gambiense* in patients 6 years of age and older and weighing at least 20 kg	TBD
Kerendia™ (finerenone) Bayer	Nonsteroidal mineralocorticoid receptor antagonist	To reduce the risk of sustained estimated glomerular filtration rate decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes	July 17, 2021
Rezurock™ (belumosudil)†* Kadmon Pharmaceuticals	Rho-associated coiled-coil kinase 2 inhibitor	Treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy	July 27, 2021
Twyneo® (tretinoin/benzoyl peroxide) Sol-Gel Technologies	Retinoid	Topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older	TBD
Vaxneuvance™ (pneumococcal 15-valent conjugate) Merck	Vaccine	Vaccine for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older	TBD

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Uptravi® (selexipag)† injection Janssen	Non-prostanoid prostacyclin agonist	Treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH	TBD

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

New biosimilars

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Semglee® (insulin glargine-yfgn)± Viatris, Biocon Biologics	Long-acting insulin	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus	End of 2021

±Interchangeable

New generics

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Feraheme® (ferumoxytol) AMAG Pharmaceuticals	Sandoz†	510 mg elemental iron per 17 mL	Iron deficiency anemia	July 16, 2021

†A-rated generic manufacturer

Indications/Label updates

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Drug name Manufacturer(s)	Type	Description
Aduhelm™ (aducanumab-avwa) Biogen	Label update	The *Indications and Usage* section of the label was updated with the following: Treatment with Aduhelm should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.
Bydureon BCise® (exenatide extended-release) AstraZeneca	Expanded indication	As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus
Dalvance® (dalbavancin) AbbVie	Expanded indication	Treatment of adult and pediatric patients with acute bacterial skin and skin structure infections caused by designated susceptible strains of certain Gram-positive microorganisms
Darzalex Faspro® (daratumumab and hyaluronidase-fihj) Janssen	Expanded indication	In combination with Pomalyst® (pomalidomide) and dexamethasone, for the treatment of adult patients with multiple myeloma in patients who have received at least one prior line of therapy including Revlimid® (lenalidomide) and a proteasome inhibitor
Drizalma Sprinkle™ (duloxetine delayed-release) Sun Pharmaceutical	New indication	Treatment of fibromyalgia in adults
Keytruda® (pembrolizumab) Merck	Indication withdrawal	Treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 as determined by a FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, human epidermal growth factor receptor 2 neu-targeted therapy

Drug name Manufacturer(s)	Type	Description
	Expanded indications	Treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC that is not curable by surgery or radiation; and treatment of patients with high-risk early-stage triple-negative breast cancer in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery
Nucala® (mepolizumab) GlaxoSmithKline	New indication	Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids
Octagam 10%® (immune globulin intravenous [human]) Octapharma	New indication	Treatment of dermatomyositis in adults
Olumiant® (baricitinib) Eli Lilly	Emergency use authorization expansion	Treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation
Opdivo® (nivolumab) Bristol Myers Squibb	Indication withdrawal	Bristol Myers Squibb plans to voluntarily withdraw the indication for Opdivo as a single agent for patients with hepatocellular carcinoma who were previously treated with Nexavar® (sorafenib)
Padcev® (enfortumab vedotin-ejfv) Seagen, Astellas Pharma	Expanded indication	Treatment of adult patients with locally advanced or metastatic urothelial cancer who: have previously received a programmed death receptor-1 or programmed death-ligand 1inhibitor and platinum-containing chemotherapy; or are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy
Prograf® (tacrolimus) Astellas Pharma	Expanded indication	Prophylaxis of organ rejection, in adult and pediatric patients receiving lung transplant in combination with other immunosuppressants
REGEN-COV™ (casirivimab/imdevimab) Regeneron	Emergency use authorization expansion	In adult and pediatric individuals (≥ 12 years of age and ≥ 40 kg) for post-exposure prophylaxis of COVID-19 in 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 individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting

Drug name Manufacturer(s)	Type	Description
Shingrix (Zoster vaccine recombinant, adjuvanted) GlaxoSmithKline	Expanded indication	Prevention of herpes zoster (HZ) in adults aged 18 years and older who are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy
Solosec® (secnidazole) Lupin	New indication	Treatment of trichomoniasis caused by *Trichomonas vaginalis* in adults

Drug recalls/Withdrawals/Shortages/Discontinuations

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Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Chantix® (varenicline) Pfizer	0.5 mg and 1 mg tablets	Recall and shortage	Pfizer suspended distribution of Chantix due to the presence of a nitrosamine, N-nitroso-varenicline. In addition, a warehouse level recall of Chantix was expanded to a consumer-level recall due to the nitrosamine. As a result, there is an ongoing shortage of Chantix. There is no estimated time frame as to when Chantix will be available. Chantix is indicated for use as an aid to smoking cessation treatment.

Drug safety news

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Drug name Manufacturer(s)	Description
Pepaxto® (melphalan flufenamide) Oncopeptides AB	The FDA alerted patients and health care professionals that a clinical trial (OCEAN, Study OP-103) evaluating Pepaxto with dexamethasone to treat patients with multiple myeloma showed an increased risk of death.
Statins	The FDA announced the request to remove the contraindication against using cholesterol-lowering statin medicines in pregnant patients. Because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients, contraindicating these drugs in all pregnant women is not appropriate.

Key guideline/Literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia - Version 2.2021	*NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia*. July 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 4.2021	*NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer*. July 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Bone Cancer*. July 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection - Version 2.2021	*NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection*. July 2021

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation - Version 3.2021	*NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation*. July 2021

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