OPTUMRx®

RxHighlights

April 2020

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Bafiertam™ (monomethyl fumarate)* Banner Life Sciences	Nrf2 pathway activator	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	TBD
MenQuadfi™ (meningococcal [Groups A, C, Y, W] conjugate vaccine) Sanofi	Vaccine	For active immunization for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y	2021
Milprosa™ (progesterone) Ferring Pharmaceuticals	Progesterone receptor agonist	To support embryo implantation and early pregnancy (up to 10 weeks post-embryo transfer) by supplementation of corpus luteal function as part of an Assisted Reproductive Technology treatment program for infertile women up to and including 34 years of age	TBD
Koselugo® (selumetinib)†* AstraZeneca, Merck	Selective MEK kinase inhibitor	Treatment of pediatric patients ≥ 2 years of age with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas	April 14, 2020
Jelmyto™ (mitomycin)† UroGen Pharma	Alkylating agent	Treatment of adult patients with low-grade upper tract urothelial cancer	June 1, 2020

Pemazyre™ (pemigatinib)†* Incyte	Selective FGFR1/2/3 inhibitor	Treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 fusion or other rearrangement as detected by an FDA-approved test	April 22, 2020
Ongentys® (opicapone)* Neurocrine Biosciences	Catechol-O-methyltransferase inhibitor	Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes	2nd half of 2020
Sevenfact® (coagulation factor VIIa [recombinant]-jncw)* LFB S.A	Recombinant human Factor VIIa	Treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors	TBD
Trodelvy™ (sacituzumab govitecan-hziy)* Immunomedics	RS7-SN-38 antibody-drug conjugate	Treatment of adult patients with metastatic triple-negative breast cancer who have received at least two prior therapies for metastatic disease	April 23, 2020
Tukysa™ (tucatinib)†* Seattle Genetics	ErbB-2 (Her-2/neu) inhibitor	Treatment of adult patients with advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting	April 21, 2020

*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
Mycamine® (micafungin) Astellas	Fresenius Kabi†	50 mg/mL, 100 mg/mL injection	Candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses or abscesses without meningoencephalitis and/or ocular dissemination; esophageal candidiasis; prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation	April 22, 2020

†A-rated generic manufacturer

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Braftovi® (encorafenib) Pfizer	New Indication	In combination with Erbitux® (cetuximab), for the treatment of adults with metastatic colorectal cancer with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy
Cymbalta® (duloxetine) Eli Lilly	Expanded indication	Treatment of fibromyalgia in patients ≥ 13 years of age
Reblozyl® (luspatercept-aamt) Bristol Myers Squibb, Acceleron Pharma	New indication	Treatment of anemia failing an erythropoiesis stimulating agent and requiring ≥ 2 red blood cell units over 8 weeks in adults with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis
Zejula® (niraparib) GlaxoSmithKline	Expanded indication	Maintenance treatment of adults with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy

Drug safety news

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Drug name Manufacturer(s)	Description
Epidiolex® (cannabidiol) GW Pharmaceuticals	GW Pharmaceuticals announced that it received notification from the Drug Enforcement Administration confirming that Epidiolex is no longer subject to the Controlled Substances Act. This change takes effect immediately. Following FDA approval, Epidiolex was initially placed in Schedule V of the CSA. Following receipt of this DEA notification, GW has filed a post-approval supplement with the FDA to remove Schedule V designation from Epidiolex. Epidiolex is approved for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients ≥ 2 years of age.
Brand and generic **Singulair®** (montelukast sodium) products	*Boxed Warnings* will be added to the drug labels for all brand and generic Singulair products regarding the risk of serious neuropsychiatric events. Singulair should only be reserved to treat allergic rhinitis in patients who are not treated effectively with or cannot tolerate other allergy medicines.

Drug recalls/withdrawals/shortages/discontinuations

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Ceftazidime injection B.Braun Medical	ceftazidime for injection (2 g) and dextrose for injection (50 ml) in Duplex container	Recall	B. Braun Medical announced a voluntary, consumer-level recall of one lot of ceftazidime and dextrose for injection because test results were found to exceed the specification limits for High Molecular Weight Polymers at the nineteen month stability interval. Ceftazidime is indicated in the treatment of lower respiratory tract infections; skin and skin-structure infections; bacterial septicemia; bone and joint infections; gynecologic infections; intra-abdominal infections; and central nervous system infections
Ketorolac injection Fresenius Kabi	30 mg/mL and 60 mg/ 2 mL vials	Recall	Fresenius Kabi announced a voluntary, user level recall of 13 lots of ketorolac injection due to the presence of particulate matter. Ketorolac is indicated for the short term management of moderately severe acute pain that requires analgesia at the opioid level

Nalbuphine injection Hospira	10 mg/mL, 20 mg/mL glass ampules 100 mg/mL (10 mg/mL), 200 mg/mL (20 mg/mL) multiple dose glass fliptop vials	Shortage	The drug shortage of Hospira's nalbuphine injection is ongoing and is due to a shortage of an active ingredient. The glass ampules are estimated to become available June 2020. The 100 mg/mL vials and the 200 mg/mL vials are estimated to become available August and November 2020, respectively. Nalbuphine is indicated for pain management that requires an opioid analgesic and for which alternative treatments are inadequate. It can also be used as a supplement to balanced anesthesia, for preoperative and postoperative analgesia, and for obstetrical analgesia during labor and delivery.
Nizatidine oral solution Amneal	15 mg/mL (75 mg/5 mL) oral solution	Recall	Amneal announced a voluntary, consumer-level recall of three lots of nizatidine oral solution because of the potential presence of NDMA levels above the acceptable daily intake levels established by the FDA. Nizatidine oral solution is used for the short-term treatment and maintenance therapy of ulcers and for the treatment of esophagitis and associated heartburn due to gastroesophageal reflux disease.
PosiFlush™ SF Saline Flush Syringe BD	10 mL syringes	Recall	BD announced a voluntary, consumer-level medical device recall of multiple lots of PosiFlush SF saline flush syringes because of holes in the packaging, which impacts package integrity and potentially compromises a sterile field. PosiFlush SF saline flush is intended to be used only for the flushing of indwelling vascular access devices.
Ranitidine products	All prescription and over-the-counter (OTC) ranitidine products	Withdrawal	The FDA announced the request to withdraw all prescription and OTC ranitidine drugs from the market immediately due to the presence of N-Nitrosodimethylamine (NDMA). Ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S
Tetracycline capsules Avet Pharmaceuticals	250 mg, 500 mg capsules	Recall	Avet announced a voluntary, consumer-level recall of eight lots of tetracycline capsules due to low out of specification dissolution test results. Tetracycline is indicated in the treatment of various infections, including respiratory infections, skin and soft tissues infections, infections caused by *Rickettsiae*, and as adjunctive therapy in severe acne.

True Metrix® Air Blood Glucose Meter Trividia Health	Glucose meter	Recall	Trividia Health announced a voluntary recall of a single True Metrix Air Blood Glucose Meter due to an incorrect factory-set unit of measure; the meter displays glucose results in mmol/L rather than mg/dL.

Key guideline/literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 4.2020	*NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer*. April 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers - Version 2.2020	*NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers*. April 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cutaneous Melanoma - Version 2.2020	*NCCN Clinical Practice Guidelines in Oncology: Cutaneous Melanoma*. April 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma - Version 2.2020	*NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma*. April 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas - Version 2.2020	*NCCN Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas*. April 2020

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas - Version 2.2020	*NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas*. April 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma - Version 2.2020	*NCCN Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma*. April 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening - Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening*. April 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain - Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain*. April 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis - Version 2.2020	*NCCN Clinical Practice Guidelines in Oncology: Antiemesis*. April 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease - Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease*. April 2020

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