OPTUMRx®

RxHighlights

December 2019

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Arazlo™ (tazarotene) lotion Bausch Health	Retinoid	Topical treatment of acne vulgaris in patients 9 years of age and older	1st half of 2020
Avsola™ (infliximab-axxq)*§ Amgen	Tumor necrosis factor alpha-inhibitor	Treatment of Crohn's disease (CD), pediatric CD, ulcerative colitis (UC), pediatric UC, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and plaque psoriasis	TBD
Caplyta® (lumateperone)* Intra-Cellular Therapies	Antipsychotic	Treatment of adult patients with schizophrenia	1st quarter 2020
Conjupri® (levamlodipine)* CSPC Pharmaceutical Group	Calcium channel blocker	Treatment of hypertension in adults and pediatric patients 6 years and older, to lower blood pressure	TBD
Dayvigo™ (lemborexant)* Eisai	Orexin receptor antagonist	Treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	March 20, 2020
Enhertu® (fam-trastuzumab deruxtecan-nxki)* Daiichi Sankyo	HER2-targeting antibody-drug conjugate	Treatment of adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting	December 20, 2019

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Ervebo® (Ebola Zaire Vaccine, Live)* Merck	Vaccine	Prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older	3rd Quarter 2020
Nouress™ (cysteine) Avadel	Sulfur-containing amino acid	As an additive to amino acids solutions to meet nutritional requirements of neonates (preterm and term infants less than one month of age) requiring total parenteral nutrition	TBD
Nplate® (romiplostim) 125 mcg injection Amgen	Thrombopoiesis-stimulating Fc-peptide fusion protein	Treatment of thrombocytopenia in adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy and treatment of pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy	November 19, 2019
Padcev™ (enfortumab vedotin-ejfv)* Seattle Genetics	Nectin-4 antagonist	Treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 or programmed death-ligand 1 inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting	December 22, 2019
RediTrex™ (methotrexate) single dose prefilled syringes Cumberland Pharmaceuticals	Dihydrofolate reductase inhibitor	Management of selected adults with severe, active rheumatoid arthritis, or children with active polyarticular juvenile idiopathic arthritis, who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents; in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis "flare" is not due to an undiagnosed concomitant disease affecting immune responses	TBD
Ubrelvy™ (ubrogepant)* Allergan	Calcitonin gene-related peptide receptor antagonist	Acute treatment of migraine with or without aura in adults	1st quarter 2020

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Vyondys 53™ (golodirsen)*† Sarepta Therapeutics	Morpholino antisense oligonucleotide	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping	December 15, 2019

*New molecular entity †Orphan Drug §Biosimilar 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
Afinitor® (everolimus) Novartis	Par†,Teva†	Par & Teva: 2.5 mg, 5 mg and 7.5 mg tablets Teva: 10 mg tablets	Treatment of hormone receptor-positive, HER2-negative breast cancer; neuroendocrine tumors; renal cell carcinoma; tuberous sclerosis complex (TSC)-associated renal angiomyolipoma; and TSC-associated subependymal giant cell astrocytoma	December 10, 2019±
Carafate® (sucralfate) Allergan	Amneal†	1 gm/10 mL oral suspension	Short-term treatment of active duodenal ulcer	December 3, 2019
NuvaRing® (etonogestrel/ethinyl estradiol) Merck	Amneal†Δ	ethinyl estradiol 0.015 mg/24h, etonogestrel 0.12 mg/24h vaginal insert	Pregnancy prevention	December 12, 2019
Travatan-Z® (travoprost) Alcon	Apotex†, Mylan†	0.004% ophthalmic solution	Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	December 18, 2019

†A-rated generic manufacturer ±Launch date for Par; Teva TBD ΔBranded generic marketed as EluRyng™

New authorized brand alternatives

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Drug name Manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Adzenys ER™ (amphetamine) Neos Therapeutics	Prasco	1.25 mg /mL extended-release oral suspension	Attention deficit hyperactivity disorder	December 23, 2019
NuvaRing® (etonogestrel/ethinyl estradiol) Merck	Prasco	ethinyl estradiol 0.015 mg/24h, etonogestrel 0.12 mg/24h vaginal insert	Pregnancy prevention	December 17, 2019
Travatan-Z® (travoprost) Alcon	Sandoz	0.004% ophthalmic solution	Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	December 18, 2019

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Fiasp® (insulin aspart) Novo Nordisk	Expanded indication	To improve glycemic control in pediatric patients with diabetes mellitus.
Lynparza® (olaparib) AstraZeneca and Merck	New indication	Maintenance treatment of adults with deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.
Mycamine® (micafungin) Astellas	Expanded indication	For the treatment of candidemia, acute disseminated candidiasis, Candida peritonitis and abscesses without meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age.
Tecentriq® (atezolizumab) Roche	Expanded indication	In combination with Abraxane® (paclitaxel protein-bound) and carboplatin, for the first-line treatment of adults with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations

Vascepa® (icosapent ethyl) Amarin Pharma	New indication	As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adults with elevated triglyceride levels and: established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for CV disease
Xtandi® (enzalutamide) Pfizer and Astellas Pharma	New indication	Treatment of metastatic castration-sensitive prostate cancer

Drug safety news

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Drug name Manufacturer(s)	Description
Gabapentin and pregabalin	The FDA warned that serious breathing difficulties may occur in patients using gabapentin (Neurontin®, Gralise®, Horizant®) or pregabalin (Lyrica®, Lyrica CR) who have respiratory risk factors.
Metformin	The FDA announced that it is investigating whether metformin in the U.S. market contains N-nitrosodimethylamine (NDMA), and whether it is above the acceptable daily intake limit of 96 nanograms.
Ranitidine and nizatidine products	The FDA announced that they are asking manufacturers of ranitidine and nizatidine products to expand their testing for the N-nitrosodimethylamine (NDMA) impurity, to include all lots of the medication before making them available to consumers. The FDA has launched an investigation to understand the cause of this impurity in these drugs and to provide information for patients and consumers who take them. As part of this investigation, the FDA has asked manufacturers to conduct their own laboratory testing to examine levels of NDMA in ranitidine and nizatidine and to send samples to the FDA for testing. Consumers may consider alternative treatments that are approved for the same or similar uses as ranitidine and nizatidine. To date, FDA's testing has not found NDMA in Pepcid® (famotidine), Tagamet® (cimetidine), Nexium® (esomeprazole), Prevacid® (lansoprazole), or Prilosec® (omeprazole).

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Accu-Chek® Aviva Plus Roche	Test strips	Recall	Roche Diabetes Care announced a voluntary, consumer-level recall of two lots of Accu-Chek Aviva Plus test strips due to the inability to perform a valid blood glucose measurement on a patient's meter with multiple strips in a given strip vial. Accu-Chek Aviva Plus test strips are used to measure and monitor blood sugar levels in people with diabetes
Flurazepam Mylan	15 mg and 30 mg capsules	Shortage	Flurazepam 15 mg capsules are now available. The 30 mg capsules are currently out of stock. Supply will be available In the first quarter of 2020. Flurazepam is indicated for the treatment of insomnia.
Gamunex-C® (immune globulin [human]) Grifols	10% injection	Withdrawal	Grifols announced two separate voluntary, consumer-level withdrawals of one lot of Gamunex-C 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; idiopathic thrombocytopenic purpura; and chronic inflammatory demyelinating polyneuropathy.
Levetiracetam Lannett	100 mg/mL oral solution	Recall	Lannett announced a voluntary, consumer-level recall of two lots of levetiracetam oral solution due to contamination with *Bacillus subtilis*. Bacillus subtilis was identified during an evaluation of a raw material used to manufacture the product. Levetiracetam is indicated for the treatment of partial-onset seizures; adjunctive therapy of myoclonic seizures in patients with juvenile myoclonic epilepsy; and primary generalized tonic-clonic seizures in patients with idiopathic generalized epilepsy.
Mirtazapine Aurobindo	7.5 mg tablets	Recall	Aurobindo announced a consumer-level recall of one lot of mirtazapine tablets due to a label error on declared strength. Bottles labeled as mirtazapine 7.5 mg may contain 15 mg tablets. Mirtazapine tablets are indicated for the treatment of major depressive disorder.

Natpara® (parathyroid hormone) Takeda	25 mcg, 50 mcg, 75 mcg, 100 mcg injection	Shortage	The drug shortage of Takeda's Natpara is ongoing due to requirements related to complying with good manufacturing processes. In September 2019, Takeda announced a voluntary patient-level recall of all doses of Natpara due to a potential issue related to rubber particulates originating from the rubber septum of the Natpara cartridge. Takeda is working with the FDA to resolve this issue. Natpara is only available through a Special Use Program that allocates Natpara to patients facing a life-threatening condition. The estimated availability of Natpara to the broader patient community is not known at this time. Natpara is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.
Ranitidine Glenmark	150 mg and 300 mg tablets	Recall	The FDA announced a voluntary, consumer-level recall of prescription ranitidine due to potential N-nitrosodimethylamine (NDMA) amounts above levels established by the FDA. Prescription ranitidine is used as a short-term treatment for active duodenal ulcers, maintenance therapy for duodenal ulcer patients, treatment of pathological hypersecretory conditions, short-term treatment of active, benign gastric ulcers, maintenance therapy for gastric ulcers, treatment of gastroesophageal reflux disease, and treatment of endoscopically diagnosed erosive esophagitis.

Key guideline/literature updates

Topic	Reference
HIV Infection Clinical Practice Guidelines – European AIDS Clinical Society	*European AIDS Clinical Society*. November 2019
Management of Hyperglycemia in Type 2 Diabetes - American Diabetes Association and the European Association for the Study of Diabetes	*Diabetes Care*. December 2019

Topic	Reference
Management of Pilondal Disease – American Society of Colon and Rectal Surgeons	*Diseases of the Colon and Rectum*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia – Version 3.2020	*NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas – Version 7.2019	*NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – Version 4.2020	*NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer – Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Colon Cancer*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cutaneous Melanoma – Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Cutaneous Melanoma*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers – Version 4.2019	*NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer – Version 4.2019	*NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer*. December 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia – Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers – Version 4.2019	*NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer – Version 2.2020	*NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas – Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer – Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis – Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms – Version 5.2019	*NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms*. December 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma – Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic – Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal – Version 3.2019	*NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities – Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities*. December 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections – Version 1.2020	*NCCN Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections*. December 2019

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