OPTUMRx®

RxHighlights

September 2018

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Ajovy™ (fremanezumab-vfrm)* Teva	Calcitonin gene-related peptide antagonist	Preventive treatment of migraine in adults	September 17, 2018
Arikayce® (amikacin liposome inhalation suspension)† Insmed	Aminoglycoside	For adults, who have limited or no alternative treatment options, for the treatment of *Mycobacterium avium complex* lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy	Early in the fourth quarter of 2018
Cassipa® (buprenorphine/naloxone) sublingual film Teva	Opioid receptor agonist (partial)/ opioid receptor antagonist	Maintenance treatment of opioid dependence	TBD
Copiktra™ (duvelisib)*† Verastem Oncology	Phosphatidylinositol 3-kinase inhibitor	Treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after at least two prior therapies; relapsed or refractory follicular lymphoma after at least two prior systemic therapies	September 27, 2018
Emgality™ (galcanezumab-gnlm)* Elli Lily	Calcitonin gene-related peptide inhibitor	Preventive treatment of migraine in adults	October 1, 2018

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Libtayo® (cemiplimab-rwlc)* Regeneron, Sanofi	Programmed death receptor-1 blocking antibody	Treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation	October 1, 2018
Lumoxiti™ (moxetumomab pasudotox-tdfk)*† Astra Zeneca	CD22 antigen inhibitor	Treatment of adult patients with relapsed or refractory hairy cell leukemia who received at least two prior systemic therapies, including treatment with a purine nucleoside analog	October 2018
Tiglutik™ (riluzole)† oral suspension ITF Pharma	Glutamate release inhibitor	Treatment of amyotrophic lateral sclerosis	September 24, 2018
Vizimpro® (dacomitinib)*† Pfizer	Kinase inhibitor	First-line treatment of patients with metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test	October 1, 2018
Xelpros™ (latanoprost) ophthalmic emulsion Sun Pharma	Prostaglandin analogue	Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	TBD

*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
Albenza® (albendazole) Impax	Cipla†, Lineage/Amneal*	200 mg tablets	Parenchymal neurocysticercosis and cystic hydatid disease	September 22, 2018

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Ampyra® (dalfampridine) Acorda Therapeutics	Accord†, Alkem Laboratories†, Aurobindo†, Mylan*, Teva†	10 mg extended-release tablets	Improve walking in patients with multiple sclerosis	September 11, 2018±
BiCNU® (carmustine) Emcure	Navinta/Zydus†	100 mg injection	Brain tumors, multiple myeloma, Hodgkin's lymphoma, and Non-Hodgkin's lymphoma	September 13, 2018
Cialis® (tadalafil) Eli Lilly	Teva†§, Prasco*	2.5 mg, 5 mg, 10 mg and 20 mg tablets	Erectile dysfunction and benign prostatic hyperplasia	September 27, 2018
Evekeo® (amphetamine) Arbor	Amneal†	5 mg and 10 mg tablets	Narcolepsy, attention deficit disorder with hyperactivity, and exogenous obesity	September 30, 2018
Forfivo XL® (bupropion) Almatica	Alvogen*, Wockhardt*	450 mg extended-release tablet	Major depressive disorder	September 27, 2018
Kristalose® (lactulose) Cumberland	Foxland†	10 g single dose packet	Constipation	September 27, 2018
Sporanox® (itraconazole) Janssen	Amneal†	10 mg/mL oral solution	Oropharyngeal and esophageal candidiasis	September 19, 2018

†A-rated generic manufacturer §Granted 180-days of marketing exclusivity *Authorized generic ±Launch date for Mylan; launch date for other manufacturers is TBD

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Actemra® (tocilizumab) subcutaneous injection Genentech	New indication	Treatment of active systemic juvenile idiopathic arthritis in patients ≥ 2 years of age
Coagadex® (coagulation Factor X [human]) Bio Products Laboratory	New and expanded indications	Treatment of adults and children with hereditary Factor X deficiency, for on-demand treatment and control of bleeding episodes, perioperative management of bleeding in patients with mild and moderate hereditary Factor X deficiency, and for routine prophylaxis to reduce the frequency of bleeding episodes.
Fycompa® (perampanel) Eisai	Expanded indication	Treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 4 years of age and older
Humira® (adalimumab) AbbVie	Expanded orphan indication	Treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older
Viramune XR® (nevirapine)	Indication update	Treatment of human immunodeficiency virus infection in patients 6 years of age or older with a body surface area of 1.17 m^2 or greater

Drug safety news

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Drug name Manufacturer(s)	Description
Dolutegravir-containing products	A new update to the *Warnings and Precautions* section of dolutegravir-containing products' drug labels will be added regarding embryo-fetal toxicity. Preliminary data from an observational study showed that dolutegravir was associated with increased risk of neural tube defects when administered at the time of conception and in early pregnancy.

Immediate-release opioids	The FDA announced updates to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS). The expanded Opioid REMS now applies to immediate-release opioid analgesics intended for use in an outpatient setting application, in addition to extended-release and long-acting opioid analgesics. The Opioid REMS program also requires that training be made available to prescribing and non-prescribing healthcare providers (eg, nurses and pharmacists) who are involved in the management of patients with pain.
Natpara® (parathyroid hormone) Shire	The *Contraindications* and *Warnings and Precautions* sections of the drug label were updated with information regarding hypersensitivity reactions.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Daklinza™ (daclatasvir) Bristol-Myers Squibb	90 mg tablets	Discontinuation	The FDA announced the discontinuation of Daklinza 90mg tablets. Bristol Myers Squibb has planned to cease distribution for Daklinza 90 mg tablets in December 2018. Daklinza is indicated for use with Sovaldi® (sofosbuvir), with or without ribavirin, for the treatment of chronic hepatitis C virus genotype 1 or genotype 3 infection.
Hexalen® (altretamine) Eisai	50 mg capsules	Discontinuation	Hexalen was discontinued as of September 24, 2018. Hexalen is indicated for use as a single agent in the palliative treatment of persistent or recurrent ovarian cancer.
Robaxin® (methocarbamol) Endo	750 mg tablets	Recall	Endo announced a voluntary, patient-level recall of two lots of Robaxin tablets because the products have been found to have incorrect daily dosing information on the label due to a labeling error which misstates the daily dose as "two to four tablets four times daily" rather than the correct dosage of "two tablets three times daily."
TRUEplus® Insulin Syringes, Leader Insulin Syringes Trividia Health	TRUEplus® 0.3cc, 29G insulin syringes and Leader 0.3cc, 31G insulin syringes	Recall	Trividia Health announced a voluntary, patient-level recall of several lots of insulin syringes because certain lots contain a defect in which a small crack in the top end of the barrel near the needle creates the inability to aspirate insulin into the syringe barrel from the insulin vial, which deems the syringe unusable.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Lynparza™ (olaparib) AstraZeneca	50 mg capsules	Discontinuation	The FDA announced the permanent discontinuation of AstraZeneca's Lynparza 50 mg capsules. The discontinuation is not due to any safety, efficacy or quality issues. Lynparza 100 mg and 150 mg tablets will continue to be available. Lynparza capsules are indicated for the treatment of deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer.
Nizoral® (ketoconazole) Janssen	2% shampoo	Discontinuation	The FDA announced the discontinuation of Nizoral shampoo. The last production of product will be in October 2018 with an expiry date of September 2020. Nizoral shampoo is indicated for the treatment of tinea (pityriasis) versicolor.
Scopolamine transdermal system Perrigo	1 mg/3 days, 4-count , 10-count and 24-count transdermal systems	Discontinuation	Perrigo has discontinued scopolamine transdermal system due to business reasons. The discontinuation is not due to product quality, safety, or efficacy concerns. Scopolamine transdermal system is indicated in adults for prevention of nausea and vomiting associated with motion sickness and for the prevention of nausea and vomiting associated with recovery from anesthesia and/or opiate analgesia and surgery.
Valsartan-containing products	Tablets	Recall update	The FDA announced an update to the ongoing investigation surrounding the recent voluntary recall of several drug products containing the active pharmaceutical ingredient valsartan. The FDA's latest testing of products shows an additional unexpected impurity in three lots of Torrent's recalled valsartan drug products. This second impurity, N-Nitrosodiethylamine (NDEA) is a known animal and suspected human carcinogen. These Torrent products were included in the company's recall on August 23, 2018. The FDA is continuing to test all products that contain valsartan for NDEA and related impurities. If the agency finds NDEA in products that have not been recalled, the FDA will work with companies to ensure all affected products are removed from the market.

Key guideline/literature updates

Topic	Reference
American College of Cardiology/American Heart Association – Management of Adults with Congenital Heart Disease	*Journal of the American College of Cardiology*. August 2018
American Academy of Neurology; the American Congress of Rehabilitation Medicine; and the National Institute on Disability, Independent Living, and Rehabilitation Research – Disorders of Consciousness	*American Academy of Neurology*. August 2018
American Society of Clinical Oncology and Infectious Diseases Society of America - Antimicrobial Prophylaxis for Adult Patients With Cancer Related Immunosuppression	*Journal of Clinical Oncology*. September 2018
American Diabetes Association – Type 1 Diabetes in Children and Adolescents	*Diabetes Care*. September 2018
U.S. Preventive Services Task Force - Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults	*Journal of the American Medical Association*. September 2018
North American Menopause Society and the Women and Mood Disorders Task Force of the National Network of Depression Centers - Evaluation and Treatment of Perimenopausal Depression	*Menopause*. October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia – Version 2.2019	*NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia*. September 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer – Version 2.2019	*NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer*. September 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities – Version 2.2018	*NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities*. September 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms – Version 1.2019	*NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative*

Topic	Reference
	Neoplasms. September 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors – Version 3.2018	*NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors*. September 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis – Version 2.2019	*NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis*. September 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Waldenström's Macroglobulinemia / Lymphoplasmacytic Lymphoma – Version 2.2019	*NCCN Clinical Practice Guidelines in Oncology: Waldenström's Macroglobulinemia / Lymphoplasmacytic Lymphoma*. September 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship – Version 2.2018	*NCCN Clinical Practice Guidelines in Oncology: Survivorship*. September 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Older Adult Oncology – Version 2.2018	*NCCN Clinical Practice Guidelines in Oncology: Older Adult Oncology*. September 2018

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