

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Asparlas™ (calaspargase pegol-mknl) [†] Servier	Asparagine specific enzyme	A component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia in pediatric and young adult patients age 1 month to 21 years	TBD
Dextenza® (dexamethasone ophthalmic insert) Ocular Therapeutix	Corticosteroid	Treatment of ocular pain following ophthalmic surgery	TBD
Elepsia™ XR (levetiracetam) extended-release tablets Sun Pharma	Synaptic vesicle protein modulator	Adjunctive therapy for the treatment of partial onset seizures in patients 12 years of age and older	TBD
Elzonris™ (tagraxofusp-erzs) [†] Stemline Therapeutics	CD123-directed cytotoxin	Treatment of blastic plasmacytoid dendritic cell neoplasm in adults and in pediatric patients 2 years and older	Early 2019
Ezallor™ (rosuvastatin) capsule Sun Pharma	HMG-CoA reductase inhibitor	As adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia or primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia); and as adjunctive therapy to other lipid-lowering treatments (eg, low-density lipoprotein [LDL] apheresis) or alone if such treatments are unavailable to reduce LDL-cholesterol, total cholesterol, and apolipoprotein B in adult patients with homozygous familial hypercholesterolemia	TBD

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Herzuma [®] (trastuzumab-pkrb) ^{*§} Teva, Celltrion	HER2/neu receptor antagonist	Adjuvant and metastatic breast cancer	TBD
Inbrija [™] (levodopa) inhalation powder Acorda Therapeutics	Dopamine precursor	Intermittent treatment of OFF episodes in people with Parkinson's disease treated with carbidopa/levodopa	First quarter of 2019
Licart [™] (diclofenac epolamine) topical system IBSA Pharma	Non-steroidal anti-inflammatory drug	Topical treatment of acute pain due to minor strains, sprains, and contusions	TBD
Motegrity [™] (prucalopride) [*] Shire	Serotonin-4 receptor agonist	Treatment of chronic idiopathic constipation in adults	2019
ProAir [®] Digihaler [™] (albuterol sulfate) Teva	Beta ₂ -adrenergic agonist	Treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease and for prevention of exercise-induced bronchospasm in patients 4 years of age and older	2019
Tolsura [™] (itraconazole) capsules Mayne Pharma	Azole antifungal	Treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients: blastomycosis, pulmonary and extrapulmonary; histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis; and aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy	December 11, 2018
Ultomiris [™] (ravulizumab-cwvz) ^{*†} Alexion	C5 complement inhibitor	Treatment of adult patients with paroxysmal nocturnal hemoglobinuria	December 24, 2018

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Vaxelis™ (diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, Haemophilus b conjugate [meningococcal protein conjugate] and hepatitis B [recombinant] vaccine) Sanofi	Vaccine	Active immunization to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to <i>Haemophilus influenzae</i> type b	TBD

*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
Aptensio XR™ (methylphenidate) Rhodes	Actavis†	10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg tablets	Attention deficit hyperactivity disorder	First half of 2019
Canasa® (mesalamine) Allergan	Mylan†§; Greenstone*	1 gm rectal suppository	Ulcerative proctitis	December 17, 2018
Elidel® (pimecrolimus) Bausch Health	Oceanside*, Teva†	1% cream	Atopic dermatitis	December 20, 2018
Ganirelix acetate Organon/Merck	Sun*	250 mcg/0.5 mL injection	Infertility	First quarter of 2019

†A-rated generic manufacturer *Authorized generic

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Envarsus XR [®] (tacrolimus) Veloxis	New indication	Prophylaxis of organ rejection in <i>de novo</i> kidney transplant patients in combination with other immunosuppressants
Keytruda [®] (pembrolizumab) Merck	New indication	Treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma
Lynparza [®] (olaparib) AstraZeneca, Merck	New indication	Maintenance treatment of deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy
Nplate [®] (romiplostim) Amgen	Expanded indication	Treatment of pediatric patients 1 year of age and older with immune thrombocytopenia
Oxtellar XR [®] (oxcarbazepine) Supernus	Expanded indication	Treatment of partial-onset seizures in patients 6 years of age and older
Ravicti [®] (glycerol phenylbutyrate) Horizon Pharma	Expanded indication	For use as a nitrogen-binding agent for chronic management of urea cycle disorders
Sprycel [®] (dasatinib) Bristol-Myers Squibb	Expanded indication	Treatment of patients ≥ 1 year of age with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia in combination with chemotherapy
Tecentriq [®] (atezolizumab) Genentech	Expanded indication	In combination with Avastin [®] (bevacizumab), paclitaxel, and carboplatin, for the first-line treatment of patients with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations

Drug name Manufacturer(s)	Type	Description
Viread[®] (tenofovir disoproxil fumarate) Gilead	Expanded indication	Treatment of chronic hepatitis B virus in patients ≥ 2 years of age weighing ≥ 10 kg

Drug safety news

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Drug name Manufacturer(s)	Description
Fluoroquinolone antibiotics	Fluoroquinolone antibiotics can increase the occurrence of rare but serious events of ruptures or tears in the aorta. These tears, called aortic dissections, or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Byvalson[™] (nebivolol/valsartan) Allergan	5 mg/80 mg tablets	Discontinuation	Allergan has discontinued Byvalson tablets. Per Allergan, there is some short-dated product currently available. Byvalson is indicated for the treatment of hypertension.
Losartan Torrent	100 mg tablets	Recall	Torrent announced a voluntary, consumer-level recall of some lots of losartan tablets due to the detection of trace amounts of an unexpected impurity, identified as N-nitrosodiethylamine, found in an active pharmaceutical ingredient manufactured by Hetero Labs.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Moxatag[®] (amoxicillin) Pragma	775 mg tablets	Discontinuation	Pragma has discontinued Moxatag extended-release tablets. The last batches of Moxatag will expire September 30, 2019. Moxatag is indicated for the treatment of tonsillitis and/or pharyngitis.
Thyrolar[®] (liotrix) Allergan	¼, ½, 1, 2, and 3 grain tablets	Discontinuation	Allergan has made a business decision to discontinue Thyrolar tablets. The discontinuation was based on a business decision and is not due to product quality, safety, or efficacy concerns. Thyrolar is indicated as replacement or supplemental therapy in patients with hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis; and as a pituitary thyroid stimulating hormone suppressant, in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, sub-acute or chronic lymphocytic thyroiditis (Hashimoto's), multinodular goiter, and in the management of thyroid cancer.
Valsartan-containing products Aurobindo	valsartan: 320 mg tablets amlodipine/valsartan: 5 mg/160 mg, 10 mg/160 mg, 5 mg/320 mg, and 10 mg/320 mg tablets valsartan/HCTZ: 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg tablets	Recall	Aurobindo announced a voluntary, consumer-level recall of several lots of valsartan, amlodipine/valsartan, and valsartan/HCTZ tablets due to the detection of trace amounts of an unexpected impurity, identified as N-nitrosodiethylamine, found in the finished drug product.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Valsartan-containing products Mylan	valsartan: 40 mg, 80 mg, 160 mg, 320 mg tablets amlodipine/valsartan: 5 mg/160 mg, 10 mg/160 mg, 5 mg/320 mg, and 10 mg/320 mg tablets valsartan/HCTZ: 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg tablets	Recall	Mylan announced a voluntary, consumer-level recall of several lots of valsartan, amlodipine/valsartan, and valsartan/HCTZ tablets due to the detection of trace amounts of an unexpected impurity, identified as N-nitrosodiethylamine, found in an active pharmaceutical ingredient manufactured by Mylan Laboratories Limited.

Key guideline/literature updates

Topic	Reference
American College of Cardiology, American Heart Association, and the Heart Rhythm Society - Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay	<i>HeartRhythm</i> . November 2018
American Academy of Pediatrics, American College of Emergency Physicians, and Emergency Nurses Association – Pediatric Readiness in the Emergency Department	<i>Pediatrics</i> . November 2018
American College of Rheumatology/National Psoriasis Foundation – Treatment of Psoriatic Arthritis	<i>Arthritis & Rheumatology</i> . December 2018
American Heart Association - Statin Safety and Associated Adverse Events	<i>Arteriosclerosis, Thrombosis, and Vascular Biology</i> . December 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer.</u> December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer – Version 3.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer.</u> December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</u> December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Penile Cancer – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Penile Cancer.</u> December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas – Version 2.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas.</u> December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</u> December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas – Version 2.2019	<u>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas.</u> December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma – Version 3.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u> December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms – Version 2.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms.</u> December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer – Version 2.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u> December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction.</u> December 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Palliative Care – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Palliative Care.</u> December 2018



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