

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Cutaquig[®] (immune globulin subcutaneous (Human) - hipp) Octapharma	Immune globulin	Replacement therapy for primary humoral immunodeficiency in adults. This includes, but is not limited to, common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.	TBD
Evekeo ODT[™] (amphetamine sulfate) Arbor Pharmaceuticals	Central nervous system stimulant	Treatment of attention deficit hyperactivity disorder in pediatric patients 6 to 17 years of age	TBD
Gloperba[®] (colchicine) oral solution Romeg Therapeutics	Alkaloid	Prophylaxis of gout flares in adults	Mid July 2019
Ontuzant[®] (trastuzumab-dttb) ^{§*} Samsung Bioepis, Merck	HER2/neu receptor antagonist	Adjuvant breast cancer; metastatic breast cancer; and metastatic gastric cancer	TBD
Tosymra[™] (sumatriptan) nasal spray Dr. Reddy's, Promius Pharma	Triptan	Acute treatment of migraine with or without aura in adults	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
Advair Diskus[®] (fluticasone propionate/salmeterol) GlaxoSmithKline	Mylan ^{†§} , Prasco [*]	Fluticasone propionate (100, 250, or 500 mcg) and salmeterol (50 mcg) as a powder formulation for oral inhalation	Asthma and chronic obstructive pulmonary disease	February 8, 2019 [¥]
Epclusa[®] (velpatasvir/sofosbuvir) Gilead	Asegua Therapeutics [*]	400 mg/100 mg tablet	Chronic hepatitis C virus	January 7, 2019
Fareston[®] (toremifene) Kyowa Kirin	Rising Pharmaceuticals [†]	60 mg tablet	Metastatic breast cancer	January 25, 2019
Harvoni[®] (ledipasvir/sofosbuvir) Gilead	Asegua Therapeutics [*]	90 mg/400 mg tablet	Chronic hepatitis C virus	January 28, 2019
ProAir[®] HFA (albuterol) Teva	Teva [*]	Inhalation aerosol: 90 mcg per actuation	Bronchospasm in patients with reversible obstructive airway disease; exercise induced bronchospasm	January 17, 2019
Rapamune[®] (sirolimus) Pfizer	VistaPharm [†]	60 mg/60 mL oral solution	Prophylaxis of organ rejection for renal transplants; lymphangiomyomatosis	January 30, 2019
Sabril[®] (vigabatrin) Lundbeck	Teva [†]	500 mg tablet	Refractory complex partial seizures; infantile spasms	January 20, 2019
Ventolin[®] HFA (albuterol) GlaxoSmithKline	Prasco [*]	Inhalation aerosol: 90 mcg per actuation	Bronchospasm in patients with reversible obstructive airway disease; exercise induced bronchospasm	January 15, 2019

†A-rated generic manufacturer *Authorized generic §Branded generic: Wixela Inhub™ ¥Launch date for Prasco; Mylan TBD

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Indications/label updates

Drug name Manufacturer(s)	Type	Description
Adacel [®] (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed) Sanofi Pasteur	Expanded indication	Active booster immunization against tetanus, diphtheria and pertussis in individuals 10 through 64 years of age. The indication was expanded for use for a repeat dose.
Alimta [®] (pemetrexed) Eli Lilly	Updated indication	In combination with Keytruda [®] (pembrolizumab) and platinum chemotherapy for the initial treatment of patients with metastatic, nonsquamous, non-small cell lung cancer, with no EGFR or ALK genomic tumor aberrations
Cabometyx [®] (cabozantinib) Exelixis	New indication	Treatment of patients with hepatocellular carcinoma who have been previously treated with Nexavar [®] (sorafenib)
Fluzone [®] Quadrivalent (influenza vaccine) Sanofi Pasteur	Updated indication	Use of the 0.5 mL dose for children 6 through 35 months of age
Imbruvica [®] (ibrutinib) AbbVie	Expanded indication	Previously untreated chronic lymphocytic leukemia/small lymphocytic lymphoma
Osphena [®] (ospemifene) Duchesnay	New indication	Treatment of moderate to severe vaginal dryness
Vfend [®] (voriconazole) Pfizer	Expanded indication	Treatment of certain fungal infections including invasive aspergillosis, candidemia, esophageal candidiasis, and serious fungal infection caused by <i>Scedosporium apiospermum</i> and <i>Fusarium spp.</i> in pediatric and adult patients

Drug safety news

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Drug name Manufacturer(s)	Description
Lartruvo [®] (olaratumab) Eli Lilly	Based on the results of a clinical study, the FDA recommends that patients who are currently receiving Lartruvo should consult with their healthcare provider about whether to remain on treatment. Furthermore, Lartruvo should not be initiated in new patients outside of an investigational study.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Adagen [®] (pegademase bovine) Leadiant Biosciences	375 mg/1.5 mL injection	Discontinuation	<p>Leadiant Biosciences discontinued Adagen due to the permanent shortage of the active ingredient. The discontinuation of the product is not due to quality, safety or efficacy concerns. Per Leadiant, inventory is estimated to runout by late-March 2019.</p> <p>Adagen is approved for enzyme replacement therapy for adenosine deaminase deficiency in patients with severe combined immunodeficiency disease who are not suitable candidates for – or who have failed – bone marrow transplantation.</p>
Ceftriaxone Lupin	250 mg, 500 mg, 1 g and 2 g injection	Recall	Lupin announced a voluntary, patient-level recall of several lots of ceftriaxone injection due to product complaints indicating grey flecks in constituted vials, identified as rubber particulate matter from the stopper.
Daklinza [™] (daclatasvir) Bristol Myers Squibb	30 mg and 60 mg tablets	Discontinuation	<p>Bristol Myers Squibb has discontinued Daklinza tablets. Previously, the FDA announced the discontinuation of Daklinza 90 mg tablets with planned distribution ceasing in December 2018. Bristol Myers Squibb has planned to cease distribution for Daklinza 30 mg and 60 mg tablets in June 2019.</p> <p>Daklinza is indicated for use with Sovaldi[®] (sofosbuvir), with or without ribavirin, for the treatment of patients with chronic hepatitis C virus genotype 1 or genotype 3 infection.</p>

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Emadine® (emedastine difumarate) Novartis	0.05% ophthalmic solution	Discontinuation	Novartis has discontinued Emadine ophthalmic solution. The discontinuation was a business decision and not due to quality, safety or efficacy concerns. Emadine is indicated for the temporary relief of the signs and symptoms of allergic conjunctivitis.
Irbesartan-containing products Prinston	irbesartan: 300 mg tablets irbesartan/HCTZ: 300 mg/12.5 mg, 150 mg/12.5 mg tablets	Recall	Prinston announced a voluntary, patient-level recall of several lots of irbesartan and irbesartan/HCTZ tablets due to the detection of trace amounts of N-nitrosodiethylamine (NDEA), found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals.
Losartan-containing products Torrent	losartan: 25 mg, 50 mg, and 100 mg tablets losartan/HCTZ: 50 mg/12.5 mg and 100 mg/12.5 mg tablets	Recall	Torrent announced a voluntary, consumer-level recall of some lots of losartan and losartan/HCTZ tablets due to the detection of trace amounts of NDEA, found in an API manufactured by Hetero Labs. This recall is an expansion to a recall that was announced in December 2018. The recall was then expanded on January 3, 2019 to include additional lots of losartan/HCTZ products.
Losartan Major	50 mg unit dose tablets	Recall	Major announced a voluntary recall of one lot of losartan tablets due to the detection of trace amounts of NDEA, found in an API manufactured by Hetero Labs.

Key guideline/literature updates

Topic	Reference
American Academy of Pediatrics – Management of Infantile Hemangiomas	<i>Pediatrics</i> . January 2019

Topic	Reference
American College of Obstetricians and Gynecologists – Gestational Hypertension and Preeclampsia	<i>Obstetrics & Gynecology</i> . January 2019
American Gastroenterological Association – Management of Mild to Moderate Ulcerative Colitis	<i>Gastroenterology</i> . February 2019
American Diabetes Association – Standard of Medical Care in Diabetes	<i>Diabetes Care</i> . January 2019
American Geriatrics Society – Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults	<i>Journal of the American Geriatrics Society</i> . January 2019
American Headache Society – Migraine Treatments	<i>Headache</i> . December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</i> . January 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia – Version 3.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia</i> . January 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma</i> . January 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors – Version 4.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors</i> . January 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer – Version 3.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer</i> . January 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary – Version 2.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Occult Primary.</u> January 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and Ovarian – Version 3.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and Ovarian.</u> January 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u> January 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain.</u> January 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Older Adult Oncology – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Older Adult Oncology.</u> January 2019



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