

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Altreno™ (tretinoin) 0.05% lotion Ortho Dermatologics	Retinoid	Topical treatment of acne vulgaris in patients 9 years of age and older	4 th quarter of 2018
Annovera™ (segesterone acetate/ethinyl estradiol)* TherapeuticsMD	Progestin/estrogen receptor agonist	Use by females of reproductive potential to prevent pregnancy	3 rd quarter of 2019
Arakoda™ (tafenoquine) 60 Degrees	Apoptosis modulator	Prophylaxis of malaria in patients ≥ 18 years of age	TBD
CEQUA™ (cyclosporine) 0.09% ophthalmic solution Sun Pharma	Immunosuppressant	To increase tear production in patients with keratoconjunctivitis sicca	TBD
Delstrigo™ (doravirine/lamivudine/tenofovir disoproxil fumarate)* Merck	NNRTI / NRTI / NRTI	A complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult patients with no prior antiretroviral treatment history	September 2018
Diacomit® (stiripentol)*† Biocodex	GABA receptor antagonist	Treatment of seizures associated with Dravet Syndrome in patients 2 years of age and older taking clobazam	TBD

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Galafold™ (migalastat) ^{††} Amicus Therapeutics	Alpha-galactosidase A enhancer	Treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene variant based on <i>in vitro</i> assay data	August 13, 2018
Inveltys™ (loteprednol etabonate) 1% ophthalmic suspension Kala	Corticosteroid	Treatment of post-operative inflammation and pain following ocular surgery	Early 2019
Jivi® (antihemophilic factor [recombinant], PEGylated-aucl) Bayer	Anithemophilic factor	Use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes	September 5, 2018
Jornay PM™ (methylphenidate) extended-release capsules Ironshore	Central nervous system stimulant	Treatment of attention deficit hyperactivity disorder in patients ≥ 6 years of age	First half of 2019
lamivudine/nevirapine/ zidovudine Micro Labs	NRTI / NNRTI / NRTI	Use alone as a complete regimen or in combination with other antiretroviral drugs for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 35 kg	TBD
Onpattro™ (patisiran) ^{††} Alnylam	RNAi therapeutic	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults	August 14, 2018
Oxervate™ (cenegermin-bkbj) ^{††} Dompé	Recombinant human nerve growth factor	Treatment of neurotrophic keratitis	Early 2019
Pifeltro™ (doravirine) [*] Merck	NNRTI	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment history	September 2018

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Poteligeo [®] (mogamulizumab-kpkc) [†] Kyowa Kirin	CCR-4 chemokine receptor antibody	Treatment of adults with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy	August 23, 2018
Takhzyro [™] (lanadelumab-flyo) [†] Shire	Kallikrein inhibitor	Prophylaxis to prevent attacks of hereditary angioedema in patients 12 years and older	August 27, 2018
Xerava [™] (eravacycline) [*] Tetraphase	Fully synthetic tetracycline antibiotic	Treatment of complicated intra-abdominal infections in patients 18 years of age and older	4 th quarter of 2018

*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
Adcirca [®] (tadalafil) Eli Lilly	Mylan ^{†§}	20 mg tablets	Pulmonary arterial hypertension	August 10, 2018
Riomet [®] (metformin) Ranbaxy	Innovida Pharmaceutique [*]	500 mg/5 mL oral solution	Type 2 diabetes mellitus	August 14, 2018
Torisel [®] (temsirolimus) Pfizer	Accord [†]	25 mg/mL injection	Advanced renal cell carcinoma	August 13, 2018
Zyclara [®] (imiquimod) Bausch Health	Oceanside [*]	3.75% cream pump	Actinic keratosis, external and perianal warts	August 21, 2018

†A-rated generic manufacturer *Authorized generic §Granted 180-days of marketing exclusivity

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Indications/label updates

Drug name Manufacturer(s)	Type	Description
Imbruvica [®] (ibrutinib) AbbVie	Expanded indication	In combination with Rituxan [®] (rituximab) for the treatment of Waldenström's macroglobulinemia
Kalydeco [®] (ivacaftor) Vertex	Expanded indication	Treatment of cystic fibrosis (CF) in patients age 12 months and older who have one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
Keytruda [®] (pembrolizumab) Merck	Expanded indication	In combination with Alimta [®] (pemetrexed) and platinum chemotherapy for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer
Lenvima [®] (lenvatinib) Eisai	New indication	First-line treatment of unresectable hepatocellular carcinoma
Nuessa [™] (metronidazole) Exeltis	Expanded indication	Treatment of bacterial vaginosis in females ≥ 12 years of age
Opdivo [®] (nivolumab) Bristol-Myers Squibb	New indication	Treatment of metastatic small cell lung cancer
Orkambi [®] (lumacaftor/ivacaftor) Vertex	Expanded indication, new formulation	Treatment of CF in patients ≥ age 2 years of age who are homozygous for the F508del mutation in the CFTR gene To support the expanded indication, Vertex launched Orkambi 100 mg/125 mg and 150 mg/188 mg oral granules
Prepopik [®] (sodium picosulfate/magnesium oxide/anhydrous citric acid) Ferring	Expanded indication	Cleansing of the colon as a preparation for colonoscopy in patients ≥ 9 years of age

Drug safety news

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Drug name Manufacturer(s)	Description
Brand and generic azithromycin	Azithromycin should not be given long-term to prevent bronchiolitis obliterans syndrome in patients with cancers of the blood or lymph nodes who undergo a donor stem cell transplant.
Sodium-glucose cotransporter-2 (SGLT-2) inhibitors	The FDA announced a new warning that cases of a rare but serious infection of the genitals and area around the genitals have been reported with the class of SGLT-2 inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. A new warning about this risk will be added to the prescribing information of all SGLT-2 inhibitors and to the patient medication guide.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
AzaSite[®] (azithromycin) Akorn	1% ophthalmic solution	Shortage	The drug shortage of AzaSite has been ongoing due to shipping delays. The estimated availability date for AzaSite is unknown at this time. AzaSite is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of certain microorganisms.
Belladonna and opium suppositories Perrigo	16.2 mg/60 mg and 16.2 mg/30 mg suppositories	Shortage	The drug shortage of belladonna and opium suppositories has been ongoing due to manufacturing delays due to a shortage of an active ingredient. The estimated availability date for belladonna and opium suppositories is October 2018. Belladonna and opium suppositories are used for relief of moderate to severe pain associated with ureteral spasm not responsive to non-narcotic analgesics and to space intervals between injections of opiates.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Erythrocin™ (erythromycin lactobionate) Hospira	500 mg injection	Shortage	Erythrocin has been unavailable due to manufacturing delays. The estimated availability date is 2019. Erythrocin is indicated in the treatment of infections caused by susceptible strains of certain organisms of various diseases. Erythrocin is also indicated for the prevention of initial attacks of rheumatic fever, prevention of recurrent attacks of rheumatic fever, and for the prevention of bacterial endocarditis.
Gamunex® -C (immune globulin [human]) Grifols	10% injection	Withdrawal	Grifols announced a voluntary, consumer-level withdrawal of one lot of Gamunex-C 10% injection due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered serious and involved the possible risk of a life-threatening situation.
Hydrochlorothiazide Accord Healthcare	12.5 mg tablets	Recall	Accord Healthcare announced a voluntary, consumer-level recall of one lot of hydrochlorothiazide (HCTZ) 12.5 mg tablets because a 100-count bottle of HCTZ tablets was found to contain 100 spironolactone 25 mg tablets.
Marplan® (isocarboxazid) Validus	10 mg tablets	Shortage	Marplan has been unavailable due to requirements related to complying with good manufacturing practices. The estimated availability date is the end of the fourth quarter of 2018. Marplan is indicated for the treatment of depression.
Montelukast Camber	10 mg tablets	Recall	The FDA announced a voluntary, patient-level recall of one lot of Camber's montelukast 10 mg tablets because sealed bottles were found to contain losartan 50 mg tablets.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Valsartan, Valsartan-Hydrochlorothiazide (HCTZ), and Amlodipine/valsartan/HCTZ Products Various manufacturers and repackagers	Valsartan: 40 mg, 80 mg, 160 mg, and 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 Amlodipine/valsartan/HCTZ: 10 mg/320 mg/25 mg, 10 mg/160 mg/25 mg, 5 mg/160 mg/12.5 mg, 10 mg/160 mg/12.5 mg, and 5 mg/160 mg/25 mg tablets	Recall	The FDA initiated a series of announcements regarding the patient-level recall of certain batches of valsartan-containing products because of unacceptable levels of a chemical known as N-nitrosodimethylamine.

Key guideline/literature updates

Topic	Reference
American Academy of Pediatrics - Diagnosis and Management of Gastroesophageal Reflux in Preterm Infants	<i>Pediatrics</i> . July 2018
American Diabetes Association – Type 1 Diabetes in Children and Adolescents	<i>Diabetes Care</i> . July 2018
American Society of Regional Anesthesia and Pain Medicine, the American Academy of Pain Medicine, and the American Society of Anesthesiologists – Use of Intravenous Ketamine Infusions for Chronic Pain	<i>Regional Anesthesia and Pain Medicine</i> . June 2018
Endocrine Society - Hypothalamic–Pituitary and Growth Disorders in Survivors of Childhood Cancer	<i>Journal of Clinical Endocrinology and Metabolism</i> . June 2018
World Health Organization – Guidelines on second-and third-line medicines and type of insulin for the control of blood glucose levels in non-pregnant adults with diabetes mellitus	<i>World Health Organization</i> . July 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Bone Cancer.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer – Version 3.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia.</i> August 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers – Version 3.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma - Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 6.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Occult Primary.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer – Version 4.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer – Version 3.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas – Version 5.2018	<i>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Waldenström's Macroglobulinemia / Lymphoplasmacytic Lymphoma - Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Waldenström's Macroglobulinemia / Lymphoplasmacytic Lymphoma.</i> August 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Lung Cancer Screening – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer- and Chemotherapy-Induced Anemia – Version 3.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Cancer- and Chemotherapy-Induced Anemia.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease.</i> August 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloid Growth Factors – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Myeloid Growth Factors.</i> August 2018



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