

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Abecma™ (idecabtagene vicleucel) ^{†*} Bristol Myers Squibb, bluebirdbio	Chimeric antigen receptor T cell therapy	Treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody	TBD
Azstarys™ (serdexmethylphenidate/ dexmethylphenidate) KemPharm	CNS stimulant	Treatment of attention deficit hyperactivity disorder in patients 6 years of age and older	Second half of 2021
Fotivda® (tivozanib) [*] AVEO Oncology	Vascular endothelial growth factor receptor tyrosine kinase inhibitor	Treatment of adult patients with relapsed or refractory advanced renal cell carcinoma following two or more prior systemic therapies	April 1, 2021
Kimyrsa™ (oritavancin) Melinta Therapeutics	Lipoglycopeptide antibiotic	Treatment of adult patients with acute bacterial skin and skin structure infections caused by susceptible isolates of the following Gram-positive microorganisms: <i>Staphylococcus aureus</i> (including methicillin-susceptible and methicillin-resistant isolates), <i>Streptococcus pyogenes</i> , <i>Streptococcus agalactiae</i> , <i>Streptococcus dysgalactiae</i> , <i>Streptococcus anginosus</i> group (includes <i>S. anginosus</i> , <i>S. intermedius</i> , and	Summer 2021

		<i>S. constellatus</i>), and <i>Enterococcus faecalis</i> (vancomycin-susceptible isolates only)	
Ponvory™ (ponesimod)* Janssen	Sphingosine 1 phosphate receptor agonist	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	March 25, 2021
Roszet® (rosuvastatin/ezetimibe) Althera Pharmaceuticals	HMG CoA-reductase inhibitor/cholesterol absorption inhibitor	An adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C) and alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia to reduce LDL-C	June 2021
Zegalogue® (dasiglucagon)* Zealand Pharma	Glucagon analog	Treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above	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
Azopt [®] (brinzolamide) Novartis	Teva [†]	1% ophthalmic suspension	Elevated intraocular pressure	March 8, 2021
Hysingla [™] ER (hydrocodone bitartrate) Purdue Pharma	Alvogen [†]	20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, 120 mg extended- release tablets	Severe pain	March 4, 2021
Xulane [®] (norelgestromin/ethinyl estradiol) Mylan	Amneal ^{†Δ±}	norelgestromin 150 mcg/ ethinyl estradiol 35 mcg per day transdermal system	Prevention of pregnancy	March 1, 2021

[†]A-rated generic manufacturer; ^ΔBranded generic is marketed as Zafemy[™]; [±]Granted 180 days of marketing exclusivity

New authorized brand alternatives

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Azopt [®] (brinzolamide) Novartis	Sandoz	1% ophthalmic suspension	Elevated intraocular pressure	March 10, 2021

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Actemra [®] (tocilizumab) Genentech	New indication	Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease
Arcalyst [®] (rilonacept) Kiniksa Pharmaceuticals	New orphan indication	Treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older
Exparel [®] (bupivacaine) Pacira BioSciences	Expanded indication	In patients aged 6 years and older for single-dose infiltration to produce postsurgical local analgesia
Fabrazyme [®] (agalsidase beta) Sanofi	Expanded indication	Treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease
Humira [®] (adalimumab) AbbVie	Expanded indication	Treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older
Ixinity [®] [(coagulation factor IX (recombinant))] Aptevo BioTherapeutics	Indication removal	The indication for routine prophylaxis in adolescents (12 years of age and older) was rescinded from the prescribing information
Keytruda [®] (pembrolizumab) Merck	Indication withdrawal	The indication for the treatment of patients with metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy was voluntarily withdrawn because a clinical study did not demonstrate statistical significance for the primary endpoint of overall survival.
Keytruda [®] (pembrolizumab) Merck	Expanded indication	In combination with platinum- and fluoropyrimidine-based chemotherapy, for the treatment of patients with locally advanced or metastatic esophageal or gastroesophageal junction carcinoma that is not amenable to surgical resection or definitive chemoradiation
Lorbrena [®] (lorlatinib) Pfizer	Expanded indication	Treatment of adult patients with metastatic non-small cell lung cancer whose tumors are anaplastic lymphoma kinase-positive

Myrbetriq® and Myrbetriq® Granules (mirabegron extended-release) Astellas	New indication, new formulation approval	Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older and weighing 35 kg or more. In addition to the new indication, the FDA also approved Myrbetriq Granules, a new oral suspension formulation. Myrbetriq Granules is approved for the treatment of NDO in pediatric patients aged 3 years and older.
Sarclisa® (isatuximab-irfc) Sanofi	New indication	In combination with Kyprolis® (carfilzomib) and dexamethasone, for the treatment of relapsed or refractory multiple myeloma in adult patients who have received one to three prior lines of therapy
Tecentriq® (atezolizumab) Roche	Indication withdrawal	Roche announced the voluntary withdrawal of the Tecentriq indication for patients with prior-platinum treated metastatic urothelial carcinoma because a clinical study did not meet the primary endpoint of overall survival.
Vyxeos® (daunorubicin and cytarabine) Jazz Pharmaceuticals	Expanded indication	Treatment of newly-diagnosed therapy-related acute myeloid leukemia or acute myeloid leukemia with myelodysplasia-related changes in adults and pediatric patients 1 year and older
Yescarta® (axicabtagene ciloleucel) Kite	New indication	Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy

Drug recalls/withdrawals/shortages/dis continuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Acyclovir injection Zydus	50 mg/mL injection	Recall	<p>Zydus announced a voluntary, user-level recall of four lots of acyclovir injection after receiving several complaints of crystallization in vials.</p> <p>Acyclovir injection is indicated for the treatment of herpes simplex infections in immunocompromised patients, severe initial clinical episodes of herpes genitalis in immuno-competent patients, herpes simplex encephalitis, neonatal herpes simplex virus infection and varicella-zoster (shingles) infections in immunocompromised patients.</p>
Bupivacaine/epinephrine injection Fresenius Kabi, Hospira	Various injection strengths	Shortage	<p>Fresenius Kabi's bupivacaine/epinephrine injection products are in shortage due to increased demand. These products are backordered, and estimated availability is April to May 2021. Hospira's bupivacaine/epinephrine injection products are in shortage due to manufacturing delays. Estimated availability is July to November 2021. Some strengths will not be available until July 2022. Fresenius Kabi and Hospira are the only manufacturers of bupivacaine/epinephrine injection products.</p> <p>Bupivacaine/epinephrine injection products are indicated for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures and for obstetrical procedures.</p>
EthyoI® (amifostine) Clinigen	500 mg per vial injection	Shortage	<p>Clinigen is the sole supplier of amifostine injection and product supply has been depleted. Clinigen estimates supply will resume in late 2021 to early 2022.</p> <p>EthyoI is indicated for the reduction of cumulative renal toxicity with chemotherapy and for the reduction of moderate to severe xerostomia from radiation of the head and neck.</p>
Gamunex-C® (immune globulin [human]) Grifols	10% injection	Withdrawal	<p>Grifols announced a voluntary, consumer-level withdrawal 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.</p> <p>There were two separate occurrences of a Gamunex-C withdrawal in March 2021.</p>

			Gamunex-C is indicated for the treatment of primary humoral immunodeficiency in patients two years of age and older; idiopathic thrombocytopenic purpura in adults and children; and chronic inflammatory demyelinating polyneuropathy in adults.
Guanfacine Apotex	2 mg extended-release tablets	Recall	Apotex announced a voluntary, consumer-level recall of three lots of guanfacine 2 mg extended-release tablets because trace amounts of quetiapine fumarate were found in one of the three lots. Guanfacine is indicated for the treatment of attention deficit hyperactivity disorder.
Phenylephrine injection Sagent	10 mg/mL injection	Recall	Sagent announced a voluntary, user-level recall of three lots of phenylephrine injection as the result of a customer complaint due to potentially loose crimped vial overseals. A non-integral crimped vial overseal may result in a non-sterile product. Phenylephrine injection is indicated for the treatment of clinically important low blood pressure resulting primarily from the dilation of blood vessels, which decreases blood pressure in the setting of anesthesia.
Telmisartan Alembic	20 mg tablets	Recall	Alembic announced a voluntary, consumer-level recall of one lot of telmisartan 20 mg tablets because of a market complaint received which stated that one bottle labeled as 30-count telmisartan 20 mg tablets, incorrectly contained 30 tablets of telmisartan 40 mg tablets. Telmisartan is indicated for the treatment of hypertension.

Key guideline/literature updates

Topic	Reference
American Academy of Dermatology and National Psoriasis Foundation – Psoriasis	<i>Journal of the American Academy of Dermatology</i> . March 2021
Advisory Committee on Immunization Practices - COVID-19 Vaccine Recommendations	<i>Morbidity and Mortality Weekly Report</i> . March 2021

Sjögren's Foundation - Pulmonary disease in Sjögren's	<u>CHEST</u> . February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</u> . March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</u> . March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</u> . March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</u> . March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers - Version 4.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers</u> . March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma</u> . March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers</u> . March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer</u> . March 2021

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Histiocytic Neoplasms - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Histiocytic Neoplasms.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 5.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 4.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> March 2021

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas - Version 4.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors – Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors.</u> March 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities.</u> March 2021



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