

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Amondys 45™ (casimersen) ^{†*} Sarepta	Antisense oligonucleotide	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping	March 1, 2021
Breyanzi® (lisocabtagene maraleucel) ^{†*} Bristol-Myers Squibb	Chimeric antigen receptor T cell therapy	Treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B	February 10, 2021
Cosela™ (trilaciclib)* G1 Therapeutics	Cyclin dependent kinase inhibitor	To decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer	February 18, 2021
Evkeeza™ (evinacumab) ^{†*} Regeneron	Angiopoietin-like 3 antagonist	Adjunct to other low-density lipoprotein-cholesterol lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia	February 17, 2021

Nulibry™ (fosdenopterin) [†] BridgeBio Pharma	Molybdenum cofactor stimulant	To reduce the risk of mortality in patients with molybdenum cofactor deficiency Type A	March 2, 2021
Pepaxto® (melfalan flufenamide) [†] Oncopeptides	Alkylating agent	In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody	March 2, 2021
Plegridy® (peginterferon beta-1a) 125 mcg/0.5mL solution in a single dose prefilled syringe for intramuscular administration Biogen	Interferon	Treatment of patients with relapsing forms of multiple sclerosis	February 2, 2021
Posimir® (bupivacaine) Durect	Local anesthetic	In adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression	TBD
Tepmetko® (tepotinib) [†] EMD Serono	C-Met receptor tyrosine kinase inhibitor	For the treatment of adult patients with metastatic non-small cell lung cancer harboring <i>mesenchymal-epithelial transition</i> exon 14 skipping alterations	February 8, 2021
Ukoniq™ (umbralisib) [†] TG Therapeutics	Phosphoinositide-3 kinase delta inhibitor	Treatment of adult patients with: relapsed or refractory marginal zone lymphoma who have received at least one prior anti-CD20-based regimen; or relapsed or refractory follicular lymphoma who have received at least three prior lines of systemic therapy	February 9, 2021

*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
Foscavir® (foscarnet) Clinigen	Fresenius Kabi†	6000 mg/250 mL injection (24 mg/mL)	Cytomegalovirus retinitis; acyclovir-resistant mucocutaneous herpes simplex virus infections	February 3, 2021
Lotemax® (loteprednol) Bausch Health	Akon†	0.5% ophthalmic gel	Post-operative inflammation and pain following ocular surgery	February 11, 2021
Northera® (droxidopa) Lundbeck	Aurobindo†, Ajanta†, Sun†, Zydus†, Ascend/Alkem†, Camber/Annora†, Novadoz/MSN†, Hikma†, Lupin†, Sciegen†, Tasman† and Teva†	100 mg, 200 mg, and 300 mg capsules	Orthostatic dizziness, lightheadedness, or the “feeling that you are about to black out” in adults with symptomatic neurogenic orthostatic hypotension	February 19, 2021‡

†A-rated generic manufacturer

‡Launch plans are pending for Lupin, Tasman and Teva; Hikma and Sciegen launched on 2/23/21

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Botox® (onabotulinumtoxinA) Allergan	New indication	Treatment of neurogenic detrusor overactivity in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication
Entresto® (sacubitril/valsartan) Novartis	Expanded indication	To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction below normal.
Gocovri® (amantadine) Adamas Pharma	New indication	Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes
Imfinzi® (durvalumab) AstraZeneca	Indication withdrawal	The indication for previously treated adult patients with locally advanced or metastatic bladder cancer was voluntarily withdrawn because a phase 3 study in the 1 st line metastatic bladder cancer setting did not meet its primary endpoints. This decision was made in consultation with the FDA.
Libtayo® (cemiplimab-rwlc) Sanofi, Regeneron	New indication	Treatment of patients with locally advanced basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor (HHI) or for whom a HHI is not appropriate; with metastatic BCC previously treated with a HHI or for whom a HHI is not appropriate The mBCC indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for the mBCC indication may be contingent upon verification and description of clinical benefit. First-line treatment of patients with non-small cell lung cancer whose tumors have high PD-L1 expression as determined by an FDA-approved test with no EGFR, ALK or ROS1 aberrations, and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic.
Nplate® (romiplostim) Amgen	New indication	Increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation
Panzyga® (immune globulin intravenous, human - ifas)	New indication	Treatment of adults with chronic inflammatory demyelinating polyneuropathy to improve neuromuscular disability and impairment

Pfizer		
Rapivab® (peramivir) Biocryst	Expanded indication	Treatment of acute uncomplicated influenza in patients 6 months and older who have been symptomatic for no more than 2 days

Drug safety news

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Drug name Manufacturer(s)	Description
Xeljanz®, Xeljanz XR (tofacitinib) Pfizer	Preliminary results from a safety clinical trial show an increased risk of serious heart-related problems and cancer with Xeljanz, Xeljanz XR (tofacitinib) compared to tumor necrosis factor inhibitors.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Enoxaparin injection Apotex	100 mg/mL and 120 mg/0.8 mL single dose syringes	Recall	<p>Apotex announced a voluntary, consumer level recall of two lots of enoxaparin injection due to a packaging error resulting in some syringes barrels containing 150 mg/mL markings (corresponding to 120 mg/0.8mL strength) instead of 100 mg/mL markings (corresponding to 100 mg/mL strength) on the syringe barrel and vice versa.</p> <p>Enoxaparin is indicated for the prophylaxis of deep vein thrombosis, treatment of acute deep vein thrombosis, prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction (MI), and for the treatment of acute ST-segment elevation MI.</p>

Key guideline/literature updates

Topic	Reference
American Academy of Dermatology and National Psoriasis Foundation - Management and Treatment of Psoriasis with Topical Therapy and Alternative Medicine Modalities for Psoriasis Severity Measures	<i>Journal of the American Academy of Dermatology</i> . February 2021
Infectious Diseases Society of America - Diagnosis and Management of Babesiosis	<i>Clinical Infectious Diseases</i> . January 2021
Pituitary Society - Agromegaly Management	<i>Pituitary</i> . February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma - Version 1.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma</i> . February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer - Version 2.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer</i> . February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 2.2021	<i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i> . February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans - Version 1.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans</i> . February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 1.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers</i> . February 2021

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kaposi Sarcoma - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Kaposi Sarcoma.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Occult Primary.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.</u> February 2021

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer – Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma) - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma).</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain.</u> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors.</u>

	February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities - Version 1.2021	<i><u>NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities.</u></i> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Palliative Care - Version 2.2021	<i><u>NCCN Clinical Practice Guidelines in Oncology: Palliative Care.</u></i> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation - Version 1.2021	<i><u>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</u></i> February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship - Version 1.2021	<i><u>NCCN Clinical Practice Guidelines in Oncology: Survivorship.</u></i> February 2021



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