

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Blenrep® (belantamab mafodotin-blmf) ^{†*} GlaxoSmithKline	Anti-BCMA antibody-drug conjugate	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent	August 9, 2020
Cystadrops® (cysteamine) Recordati Rare Diseases	Cystine-depleting agent	Treatment of corneal cystine crystal deposits in adults and children with cystinosis	September 3, 2020
Enbrel® (etanercept) 0.25 mg/0.5mL single dose vial Amgen	Tumor necrosis factor-alpha inhibitor	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis	July 21, 2020
Enspryng™ (satralizumab-mwge) ^{†*} Genentech	Interleukin-6 monoclonal antibody	Treatment of neuromyelitis optica spectrum disorder in adult patients who are anti-aquaporin-4 antibody positive	August 17, 2020
Evrysdi™ (risdiplam) ^{†*} Genentech	Motor neuron 2 (SMN2) splicing modifier	Treatment of spinal muscular atrophy in patients 2 months of age and older	August 10, 2020

Kesimpta® (ofatumumab) Genmab and Novartis	CD20 monoclonal antibody	For the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.	August 20, 2020
Lampit® (nifurtimox) [†] Bayer	Anti-parasitic, anti-protozoal	In pediatric patients (birth to less than 18 years of age and weighing at least 2.5 kg) for the treatment of Chagas disease, caused by <i>Trypanosoma cruzi</i>	TBD
Olinvyk™ (oliceridine)* Trevena	Opioid receptor agonist	In adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate	Fourth quarter of 2020
Onureg® (azacitidine oral tablets) [†] Bristol-Myers Squibb	DNA methylation inhibitor	For the continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or CR with incomplete blood count recovery following intensive induction chemotherapy and who are not able to complete intensive curative therapy	September 02, 2020
Sogroya® (somapacitan-beco) Novo Nordisk	Recombinant human growth hormone (rhGH)	For replacement of endogenous growth hormone in adults with growth hormone deficiency	TBD
Viltepso™ (viltolarsen) ^{†*} NS Pharma	Morpholino antisense oligonucleotide	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping	August 17, 2020
Winlevi® (clascoterone) Cassiopea	Androgen antagonist	Topical treatment of acne vulgaris in patients 12 years of age and older	Early 2021
Xaracoll® (bupivacaine) Innocoll	Sodium channel blocker	In adults for placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair	TBD

Xtandi® (enzalutamide) tablets Astellas	Androgen receptor antagonist	Treatment of patients with castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer	TBD
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*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
Ciprodex® (ciprofloxacin/dexamethasone) Alcon	Dr. Reddy†	0.3% / 0.1% otic suspension	Acute otitis externa; acute otitis media in pediatric patients with tympanostomy tubes	August 11, 2020
Emtriva® (emtricitabine) Gilead	Cipla†	200 mg capsules	Human immunodeficiency virus-1 (HIV-1) infection	August 31, 2020
Jadenu® Sprinkle (deferasirox) Novartis	Ascend†	90 mg, 180 mg, and 360 mg granules	Chronic iron overload due to blood transfusions and non-transfusion-dependent thalassemia syndromes	August 5, 2020
Moviprep® (polyethylene glycol 3350/ sodium sulfate/sodium chloride/potassium chloride/ascorbic acid/sodium ascorbate) Salix	Teva†	1 carton containing two pouches labeled Pouch A and 2 pouches labeled Pouch B. Each Pouch A contains 100 grams of polyethylene glycol 3350, 7.5 grams of sodium sulfate, 2.691 grams of sodium	For cleansing of the colon as a preparation for colonoscopy in adults	August 31, 2020

		chloride, and 1.015 grams of potassium chloride; Each Pouch B contains 4.7 grams of ascorbic acid and 5.9 grams of sodium ascorbate		
Protonix® (pantoprazole) Pfizer	Sun Pharma†	40 mg packet for oral suspension	Erosive esophagitis and pathological hypersecretory conditions	August 13, 2020
Tecfidera® (dimethyl fumarate) Biogen	Mylan†	120 mg and 240 mg delayed-release capsules	Multiple sclerosis	August 19, 2020
Symfi®/Symfi Lo® (efavirenz/lamivudine/tenofovir disoproxil fumarate) Mylan	Laurus Labs†	efavirenz/ lamivudine/ tenofovir disoproxil fumarate: 600/300/300 mg and 400/300/300 mg tablets	HIV-1 infection	August 28, 2020

†A-rated generic manufacturer

New authorized brand alternatives

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Sprix® (ketorolac) Zyla Life Sciences	Prasco	15.75 mg nasal spray	Short term management of moderate to moderately severe pain that requires analgesia at the opioid level	May 6, 2020
Ciprodex® (ciprofloxacin/dexamethasone) Alcon	Sandoz	0.3% / 0.1% otic suspension	Acute otitis externa; acute otitis media in pediatric patients with tympanostomy tubes	August 12, 2020

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Darzalex® (daratumumab) and Kyprolis® (carfilzomib) Amgen	Expanded indication	The combination use of Darzalex with Kyprolis and dexamethasone in adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
Dovato® (dolutegravir/lamivudine) ViiV Healthcare	Expanded indication	As a complete regimen for the treatment of human immunodeficiency virus type 1 infection in adults with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Dovato
Mirena® (levonorgestrel-releasing intrauterine system) Bayer	Expanded indication	Prevention of pregnancy for up to 6 years; replace after the end of the sixth year

Spravato® (esketamine) Janssen	New indication	In conjunction with an oral antidepressant, to treat depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior
Suprep® Bowel Prep Kit (sodium sulfate/potassium sulfate/magnesium sulfate) Braintree	Expanded indication and new strength	Cleansing of the colon in preparation for colonoscopy in adult and pediatric patients 12 years of age and older. Suprep Bowel Prep Kit pediatric strength will be available as 2 bottles containing 4.5 ounces of oral solution.
Xeomin® (incobotulinumtoxinA) Merz	Expanded indication	Treatment or improvement of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
Xyntha® and Xyntha Solofuse® (antihemophilic factor [recombinant]) Wyeth	New indication	Use in adults and children with hemophilia A (congenital factor VIII deficiency) for routine prophylaxis to reduce the frequency of bleeding episodes
Ultravate® (halobetasol propionate) Sun Pharmaceuticals	Expanded indication	Topical treatment of plaque psoriasis in patients twelve years of age and older

Drug safety news

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Drug name Manufacturer(s)	Description
Invokana® (canagliflozin), Invokamet® (canagliflozin/metformin) and Invokamet XR (canagliflozin/metformin extended-release)	The boxed warnings for Invokana, Invokamet and Invokamet XR were updated to remove information regarding lower limb amputation and the albuminuria condition for continued dosing of patients whose estimated glomerular filtration rate falls between 30 and less than 45 mL/min/1.73 m ² .
Rifampin and Priftin® (rifapentine)	The FDA announced that there are nitrosamine impurities in certain samples of rifampin and Priftin. Patients taking these medicines should continue taking their current medicine and consult with their health care professional about any concerns.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
DDAVP®, desmopressin acetate, and Stimate® nasal spray products Ferring	DDAVP & desmopressin acetate: 10 mcg/0.1 mL nasal spray Stimate: 1.5 mg/mL nasal spray	Recall	<p>Ferring announced a voluntary, consumer-level recall of several lots of DDAVP, desmopressin acetate, and Stimate nasal spray products due to superpotency.</p> <p>DDAVP and desmopressin nasal sprays are indicated as antidiuretic replacement therapy in the management of central cranial diabetes insipidus and for management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.</p> <p>Stimate nasal spray is indicated for the treatment of patients with hemophilia A with Factor VIII coagulant activity levels greater than 5% and for the treatment of patients with mild to moderate classic von Willebrand's disease (Type I) with Factor VIII levels greater than 5%.</p>
Lacrisert® (hydroxypropyl cellulose) Bausch Health	Ophthalmic insert	Shortage	<p>The drug shortage of Lacrisert ophthalmic insert is ongoing. Per Bausch Health, Lacrisert is on back order due to manufacturing interruptions caused by the COVID-19 pandemic. Lacrisert may not be available until the latter part of the third quarter of 2020.</p> <p>Lacrisert is indicated in patients with moderate to severe dry eye syndromes, including keratoconjunctivitis sicca. Lacrisert is indicated especially in patients who remain symptomatic after an adequate trial of therapy with artificial tear solutions.</p>
Metformin extended-release (ER) Bayshore	500 mg, 750 mg tablets	Recall	<p>Bayshore announced a voluntary, consumer-level recall of two lots of metformin ER 500 mg and 750 mg tablets due to the detection of N-nitrosodimethylamine (NDMA) levels in excess of the acceptable daily intake limit.</p> <p>Metformin ER tablets are indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus.</p>

<p>Nature-Throid® (thyroid), WP Thyroid® (thyroid), and Westhroid™ (thyroid)</p> <p>RLC Labs</p>	<p>Nature-Throid: 32.5 mg, 48.75 mg, 65 mg, 81.25 mg, 97.5 mg, 113.75 mg, 130 mg, 146.25 mg, 162.5 mg, and 195 mg tablets</p> <p>WP Thyroid: 16.25 mg, 32.5 mg, 48.75 mg, 65 mg, 81.25 mg, 97.5 mg, 113.75 mg, and 130 mg tablets</p> <p>Westhroid: 32.5 mg and 65 mg tablets</p> <p>*Nature-Throid and Westhroid are identical formulations. Westhroid products are marketed as Nature-Throid.</p>	<p>Recall</p>	<p>RLC Labs announced a voluntary, consumer-level recall of all unexpired lots of Nature-Throid and WP Thyroid tablets because some lots contain less than the required 90% of the active ingredient.</p> <p>Nature-Throid, Westhroid and WP Thyroid tablets are used for various types of hypothyroidism; as pituitary thyroid stimulating hormone suppressants, in the treatment or prevention of various types of goiters, and in the management of thyroid cancer; and as diagnostic agents</p>
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Key guideline/literature updates

Topic	Reference
<p>American Society of Hematology Guidelines for Sickle Cell Disease – Management of Acute and Chronic Pain</p>	<p><i>Blood Advances</i>. June 2020</p>
<p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 4.2020</p>	<p><i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i>. August 2020</p>

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia - Version 2.2021	<i><u>NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia.</u></i> August 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 4.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</u></i> August 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 3.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer.</u></i> August 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 5.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</u></i> August 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 1.2021	<i><u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u></i> August 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes - Version 3.2021	<i><u>NCCN Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes.</u></i> August 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 1.2021	<i><u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u></i> August 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection - Version 2.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u></i> August 2020

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology:
Cancer in People Living with HIV - Version 2.2020

[NCCN Clinical Practice Guidelines in Oncology: Cancer in People Living with HIV.](#)

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