

## New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Abrilada</b> <sup>™</sup> (adalimumab-afzb) <sup>*§</sup> Pfizer	Tumor necrosis factor inhibitor	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, and plaque psoriasis	November 2023
<b>Absorica</b> <sup>®</sup> LD <sup>™</sup> (isotretinoin) capsules Sun Pharmaceuticals	Retinoid	Treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with its use, Absorica LD is reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics	TBD
<b>Adakveo</b> <sup>®</sup> (crizanlizumab) <sup>*†</sup> Novartis	P-selectin antagonist	To reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease	November 19, 2019
<b>Brukinsa</b> <sup>™</sup> (zanubrutinib) <sup>*†</sup> BeiGene	Selective inhibitor of Bruton tyrosine kinase	Treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy	November 18, 2019
<b>Exservan</b> <sup>®</sup> (riluzole) <sup>†</sup> oral film Aquestive Therapeutics	Glutamate release inhibitor	Treatment of amyotrophic lateral sclerosis	TBD

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<b>Fetroja</b> <sup>®</sup> (cefiderocol)* Shionogi, GlaxoSmithKline	Cephalosporin antibiotic	Treatment of patients 18 years of age or older with complicated urinary tract infections, including kidney infections caused by susceptible Gram-negative microorganisms, who have limited or no alternative treatment options	Early 2020
<b>Fluzone</b> <sup>®</sup> High-Dose <b>Quadrivalent</b> (influenza vaccine) Sanofi	Influenza vaccine	For active immunization for the prevention of influenza caused by influenza A subtype viruses and type B viruses contained in the vaccine. Fluzone High-Dose Quadrivalent is indicated for use in persons 65 years of age and older.	Fall 2020
<b>Givlaari</b> <sup>®</sup> (givosiran)* <sup>†</sup> Alnylam	RNAi therapeutic agent	Treatment of adults with acute hepatic porphyria	November 24, 2019
<b>Ibrance</b> <sup>®</sup> (palbociclib) tablets Pfizer	Cyclin-dependent kinase inhibitor	Treatment of adult patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer in combination with: an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or fulvestrant in patients with disease progression following endocrine therapy	TBD
<b>Olumiant</b> <sup>®</sup> (baricitinib) 1 mg tablet Eli Lilly, Incyte	Janus associated kinase 1/2 inhibitor	Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor antagonist therapies	October 31, 2019
<b>Oxbryta</b> <sup>™</sup> (voxelotor)* <sup>†</sup> Global Blood Therapeutics	Hemoglobin modulator	Treatment of sickle cell disease in adults and pediatric patients 12 years of age and older	November 27, 2019
<b>Talicia</b> <sup>®</sup> (omeprazole/amoxicillin/rifabutin) RedHill Biopharma	Proton pump inhibitor/penicillin/ RNA polymerase inhibitor	Treatment of <i>Helicobacter pylori</i> infection in adults	1 <sup>st</sup> quarter of 2020
<b>Truxima</b> <sup>®</sup> (rituximab-abbs)* <sup>§</sup> Teva, Celltrion	Monoclonal antibody	Treatment of non-Hodgkin's lymphoma and chronic lymphocytic leukemia	November 7, 2019

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<b>Reblozyl</b> <sup>®</sup> (luspatercept-aamt) <sup>*†</sup> Celgene, Acceleron	Erythroid maturation agent	Treatment of anemia in adult patients with beta thalassemia who require regular red blood cell transfusions	November 15, 2019
<b>Xcopri</b> <sup>®</sup> (cenobamate) <sup>*</sup> SK Biopharmaceuticals	--	Treatment of partial-onset seizures in adult patients	2nd quarter of 2020
<b>Ziextenzo</b> <sup>™</sup> (pegfilgrastim-bmez) <sup>*§</sup> Sandoz	Colony-stimulating factor	To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	November 8, 2019

\*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
<b>Apriso</b> <sup>®</sup> (mesalamine) Bausch Health	Mylan <sup>†</sup>	375 mg extended-release capsules	Maintenance of remission of ulcerative colitis in patients	November 27, 2019
<b>Jadenu</b> <sup>®</sup> (deferasirox) Novartis	Alembic <sup>†</sup> , Dr.Reddy's/MSN Laboratories <sup>†</sup> , Teva, Zydus <sup>†</sup>	90 mg and 360 mg tablets	Chronic iron overload due to blood transfusions; chronic iron overload in non-transfusion-dependent thalassemia syndromes	November 21, 2019*

†A-rated generic manufacturer  
\*Alembic launched November 21, 2019; Other Manufacturers launched November 25, 2019

## Indications/label updates

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Drug name Manufacturer(s)	Type	Description
<b>Calquence</b> <sup>®</sup> (acalabrutinib) AstraZeneca	New indication	Treatment of adults with chronic lymphocytic leukemia or small lymphocytic lymphoma
<b>Keppra</b> <sup>®</sup> (levetiracetam), <b>Keppra XR</b> <sup>™</sup> (levetiracetam) UCB Pharma	Expanded indication	Treatment of partial onset seizures
<b>Sorilux</b> <sup>®</sup> (calcipotriene) Mayne Pharma	Expanded indication	Topical treatment of plaque psoriasis of the scalp and body in patients 4 years of age and older
<b>Toujeo</b> <sup>®</sup> (insulin glargine) Sanofi	Expanded indication	To improve glycemic control in adults and pediatric patients 6 years and older with diabetes mellitus

## Drug safety news

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Drug name Manufacturer(s)	Description
Laboratory analysis of ranitidine and nizatidine products	<p>Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, provided an update regarding the ongoing investigation of the N-Nitrosodimethylamine (NDMA) impurity in prescription and over-the-counter ranitidine products.</p> <p>The FDA has tested numerous ranitidine and nizatidine products over the past few months and has released a summary of the NDMA levels of these products to date. The FDA concludes that the NDMA levels are similar to the NDMA levels expected from consuming common foods like grilled or smoked meats. The FDA will provide more information as soon as it is available.</p>

## Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
<b>Erwinaze®</b> (asparaginase <i>Erwinia chrysanthemi</i> ) Jazz	10,000 IU lyophilized powder	Shortage	<p>The drug shortage of Jazz's Erwinaze is ongoing. Jazz estimates product will be available for ordering by December.</p> <p>Erwinaze is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia who have developed hypersensitivity to <i>E. coli</i>-derived asparaginase.</p>
<b>Gamunex-C®</b> (immune globulin [human]) Grifols Therapeutics	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>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.</p>
<b>Ranitidine</b> Golden State Medical Supply, Aurobindo, Amneal, AvKare, American Health Packaging, and Precision Dose	150 mg, 300 mg tablets; 150 mg, 300 mg capsules; or 15 mg/mL oral solution products	Recall	<p>The FDA announced voluntary, consumer-level recalls of various prescription ranitidine products due to N-nitrosodimethylamine (NDMA) contamination.</p> <p>Ranitidine is an OTC and prescription drug. Ranitidine is an H2 (histamine-2) blocker, which decreases the amount of acid created by the stomach.</p>
<b>0.9% sodium chloride irrigation</b> Baxter	5000 mL arthromatic plastic container	Recall	<p>Baxter announced a consumer-level recall of one lot of sodium chloride irrigation due to the potential presence of leaks.</p> <p>Sodium chloride irrigation is used as an arthroscopic irrigating fluid with endoscopic instruments during arthroscopic procedures requiring distension and irrigation of the knee, shoulder, elbow, or other bone joints.</p>

## Key guideline/literature updates

Topic	Reference
Secondary Fracture Prevention Guidelines – American Society for Bone and Mineral Research	<a href="#"><i>American Society for Bone and Mineral Research</i></a> . September 2019
Diagnosis and Treatment of Adults with Community-Acquired Pneumonia - American Thoracic Society and Infectious Diseases Society of America	<a href="#"><i>American Journal of Respiratory and Critical Care Medicine</i></a> . October 2019
Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents – American Academy of Pediatrics	<a href="#"><i>Pediatrics</i></a> . October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma – Version 1.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma</i></a> . November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas – Version 6.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i></a> . November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer – Version 1.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</i></a> . November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer – Version 4.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer</i></a> . November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers – Version 3.2019	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers</i></a> . November 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer – Version 3.2019	<a href="#"><i><u>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer.</u></i></a> November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma – Version 1.2020	<a href="#"><i><u>NCCN Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma.</u></i></a> November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer – Version 1.2020	<a href="#"><i><u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u></i></a> November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer – Version 3.2019	<a href="#"><i><u>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.</u></i></a> November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma – Version 1.2020	<a href="#"><i><u>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma.</u></i></a> November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia – Version 2.2020	<a href="#"><i><u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia.</u></i></a> November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer – Version 2.2020	<a href="#"><i><u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u></i></a> November 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Testicular Cancer – Version 2.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer.</i></a> November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas – Version 1.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas.</i></a> November 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors – Version 1.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors.</i></a> November 2019



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