

## New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Gemtesa</b> <sup>®</sup> (vibegron)* Urovant Sciences	Selective beta 3 adrenergic receptor agonist	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults	1 <sup>st</sup> quarter of 2021
<b>Hetlioz LQ</b> <sup>™</sup> (tasimelteon) oral suspension Vanda Pharmaceuticals	Melatonin receptor 1 and 2 agonist	Treatment of nighttime sleep disturbances in Smith-Magenis Syndrome in pediatric patients 3 to 15 years of age	1 <sup>st</sup> quarter of 2021
<b>Imcivree</b> <sup>™</sup> (setmelanotide) <sup>†</sup> Rhythm Pharmaceuticals	Melanocortin 4 receptor agonist	For chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance	December 22, 2020
<b>Klisyri</b> <sup>®</sup> (tirbanibulin)* Athenex	Src kinase and tubulin inhibitor	Topical treatment of actinic keratosis of the face or scalp	1 <sup>st</sup> quarter of 2021

<p><b>Margenza™</b> (margetuximab-cmkb)* MacroGenics</p>	<p>HER2 oncoprotein antagonist</p>	<p>In combination with chemotherapy, for the treatment of adult patients with metastatic human epidermal growth factor receptor 2 protein (HER2)-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease</p>	<p>March 2021</p>
<p><b>Orgovyx™</b> (relugolix)* Myovant Sciences'</p>	<p>Gonadotropin-releasing hormone receptor antagonist</p>	<p>Treatment of adult patients with advanced prostate cancer</p>	<p>December 22, 2020</p>
<p><b>Orladeyo™</b> (berotralstat)<sup>†</sup> BioCryst Pharmaceuticals</p>	<p>Kallikrein inhibitor</p>	<p>Prophylaxis to prevent attacks of hereditary angioedema in adults and pediatric patients 12 years of age and older.</p>	<p>December 8, 2020</p>
<p><b>Retacrit™</b> (epoetin alfa-epbx)<sup>§</sup> multiple-dose vials Hospira, Pfizer</p>	<p>Erythropoiesis-stimulating agent</p>	<p>Treatment of anemia due to chronic kidney disease, chemotherapy, or use of zidovudine in patients with human immunodeficiency virus-infection; Reduce the need for allogeneic red blood cell transfusions among patients with perioperative hemoglobin &gt; 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery</p>	<p>November 12, 2020</p>
<p><b>Riabni™</b> (rituximab-arrx)<sup>*§</sup> Amgen</p>	<p>Monoclonal antibody</p>	<p>Treatment of relapsed or refractory, low grade or follicular, CD20-positive B-cell non-Hodgkin's lymphoma (NHL) as a single agent; previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy; non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone chemotherapy; previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) or other anthracycline-based chemotherapy regimens; previously untreated and previously treated CD20-positive chronic lymphocytic leukemia in combination with fludarabine and cyclophosphamide; and granulomatosis with polyangiitis</p>	<p>December 23, 2020</p>

		(Wegener's Granulomatosis) and microscopic polyangiitis in adult patients in combination with glucocorticoids	
<b>Thyquidity™</b> (levothyroxine sodium) Reguliance/Vertice Specialty Group	Thyroid hormone	Replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism; adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer	TBD

\*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>Entereg®</b> (alvimopan) Merck	Teva†	12 mg capsules	Accelerate time to upper and lower gastrointestinal recovery following surgeries that include partial bowel resection with primary anastomosis	December 1, 2020
<b>Glucagon® Emergency Kit for Low Blood Sugar</b> (glucagon) Eli Lilly	Amphastart†	1 mg/vial	Severe hypoglycemia; diagnostic aid	1 <sup>st</sup> quarter of 2021
<b>Ofirmev®</b> (acetaminophen) Mallinckrodt	Leucadia Pharmaceutical†, Auromedics/Aurobindo†, Sandoz† and Mylan†	10 mg/mL intravenous solution	Management of mild to moderate pain; management of moderate to severe pain with adjunctive opioid analgesics; and reduction of fever	December 7, 2020§
<b>Saphris®</b> (asenapine) Allergan	Breckenridge€†, Alembic€† and Sigmapharm€†	2.5 mg, 5 mg, and 10 mg sublingual tablets	Schizophrenia; bipolar disorder	December 11, 2020,
<b>Vivlodex®</b> (meloxicam) Assertio	Lupin†	5 mg and 10mg capsules	Osteoarthritis pain	December 17, 2020

†A-rated generic manufacturer; TBD: to be determined  
§Mylan launch TBD; €Breckenridge launched 2.5 mg and 10 mg strengths; Alembic and Sigmapharm launched 5 mg and 10 mg strengths

## New authorized brand alternatives

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Saphris®</b> (asenapine) Allergan	Greenstone	2.5 mg, 5 mg, 10 mg sublingual tablets	Schizophrenia; bipolar disorder	December 11, 2020,

## Indications/label updates

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Drug name Manufacturer(s)	Type	Description
<b>Arcalyst®</b> (rilonacept) Regeneron	New indication	Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist in adults and pediatric patients weighing at least 10 kg
<b>Benlysta®</b> (belimumab) GlaxoSmithKline	New indication	Treatment of adult patients with active lupus nephritis who are receiving standard therapy
<b>Gavreto™</b> (pralsetinib) Blueprint Medicines	New orphan indications	Treatment of patients 12 years of age and older with advanced or metastatic rearranged during transfection (RET)-mutant medullary thyroid cancer who require systemic therapy and patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory
<b>Hetlioz®</b> capsules Vanda Pharmaceuticals	New orphan indication	Treatment of nighttime sleep disturbances in Smith-Magenis Syndrome in patients 16 years of age and older
<b>Iclusig®</b> (ponatinib) Takeda	Expanded indication	Treatment of adult patients with chronic phase chronic myeloid leukemia with resistance or intolerance to at least two prior kinase inhibitors
<b>Kineret®</b> (anakinra) Swedish Orphan Biovitrum	New indication	Treatment of Deficiency of Interleukin-1 Receptor Antagonist

<b>Opdivo</b> <sup>®</sup> (nivolumab) Bristol Myers Squibb	Indication withdrawal	The indication, for the treatment of patients with metastatic small cell lung cancer with progression after platinum-based chemotherapy and at least one other line of therapy, was withdrawn because the primary endpoints of overall survival were not met in certain clinical studies.
<b>Saxenda</b> <sup>®</sup> (liraglutide) Novo Nordisk	Expanded indication	Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 years and older with: body weight above 60 kg and an initial body mass index corresponding to 30 kg/m <sup>2</sup> or greater for adults by international cut-offs
<b>Tagrisso</b> <sup>®</sup> (osimertinib) AstraZeneca	New indication	Adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
<b>Trikafta</b> <sup>®</sup> (elexacaftor/tezacaftor/ivacaftor; ivacaftor), <b>Symdeko</b> <sup>®</sup> (tezacaftor/ivacaftor; ivacaftor) and <b>Kalydeco</b> <sup>®</sup> (ivacaftor) Vertex	Expanded indication, label updates	Treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data  Symdeko and Kalydeco received approvals to include additional responsive mutations in people with CF ages 6 years and older and age 4 months and older, respectively.
<b>Xeomin</b> <sup>®</sup> (incobotulinumtoxinA) Merz Pharmaceuticals	Expanded indication	Treatment of chronic sialorrhea in patients 2 years of age and older
<b>Xolair</b> <sup>®</sup> (omalizumab) Genentech	New indication	Add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids
<b>Xpovio</b> <sup>®</sup> (selinexor) Karyopharm Therapeutics	Expanded indication	In combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy

## Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
<b>Anagrelide</b> Torrent	1 mg capsules	Recall	Torrent announced a voluntary, user level recall of one lot of anagrelide 1 mg capsules due to dissolution test failure detected during routine quality testing.  Anagrelide is a platelet-reducing agent indicated for the treatment of patients with thrombocythemia, to reduce the risk of thrombosis and associated symptoms including thrombo-hemorrhagic events.
<b>Heparin sodium in 5% dextrose</b> B. Braun Medical	20,000 units per 500 mL in 5% dextrose injection; 25,000 units per 500 mL in 5% dextrose injection; 25,000 units per 250 mL in 5% dextrose injection	Withdrawal	B. Braun Medical announced a voluntary, consumer-level withdrawal of several lots of heparin sodium in 5% dextrose injection because of ongoing changes that B. Braun is performing to ensure their heparin products meet certain potency requirements.  To avoid potential market shortages, B. Braun is withdrew heparin in dextrose products in two phases. This is the second phase of the withdrawal. The first phase was announced in July 2020. B. Braun is not anticipating any major potential for supply disruption.  Heparin is indicated for prophylaxis and treatment of venous thrombosis and pulmonary embolism, thromboembolic complications associated with atrial fibrillation; treatment of acute and chronic consumption coagulopathies; prevention of clotting in arterial and cardiac surgery; prophylaxis and treatment of peripheral arterial embolism; and anticoagulant use in blood transfusions, extracorporeal circulation, and dialysis procedures.
<b>Ketorolac</b> Fresenius Kabi	60 mg/2 mL, 2 mL fill in a 2 mL amber vial; 30 mg/mL 1 mL fill in a 2 mL amber vial	Recall	Fresenius Kabi announced a voluntary, user level recall of one lot of ketorolac 60 mg/2 mL injection and one lot of ketorolac 30 mg/1 mL injection, due to particulate matter.  Ketorolac tromethamine is indicated for the short-term management of moderately severe acute pain that requires analgesia at the opioid level, usually in a postoperative setting.
<b>Paroex®</b> (chlorhexidine gluconate) Sunstar Americas	0.12% oral rinse	Recall	Sunstar America announced a voluntary, consumer level recall of Paroex, labeled with expiration dates of 12/31/20 – 9/30/22, due to

			<p>contamination with <i>Burkholderia lata</i>. This is an expansion of the recall initially announced on October 27, 2020.</p> <p>Paroex is indicated for use as part of a professional program for the treatment of gingivitis.</p>
<p><b>Chlorhexidine gluconate</b> Precision Dose</p>	0.12% oral rinse	Recall	<p>Precision Dose is voluntarily recalling all lots of chlorhexidine gluconate oral rinse unit dose cups bearing an expiration date from 1/31/2021 – 02/28/2022 to the consumer level. Precision Dose was notified by the manufacturer, Sunstar Americas, that this product may be contaminated with the bacteria <i>Burkholderia lata</i>.</p> <p>Chlorhexidine gluconate is indicated for use as part of a professional program for the treatment of gingivitis.</p>
<p><b>Regenecare® HA Hydrogel</b> (lidocaine) MPM Medical</p>	2% topical gel	Recall	<p>MPM Medical announced a voluntary, consumer level recall of one lot of Regenecare HA Hydrogel, due to contamination with <i>Burkholderia cepacia</i>.</p> <p>Regenecare HA Hydrogel is an over-the-counter product used for temporary relief of pain and itching.</p>
<p><b>Sildenafil and Trazodone</b> AvKare</p>	<p>Sildenafil: 100 mg tablets</p> <p>Trazodone: 100 mg tablets</p>	Recall	<p>AvKare announced a voluntary recall of one lot of sildenafil 100 mg tablets and one lot of trazodone 100 mg tablets because of mixed product. A bottle of sildenafil contained trazodone tablets and a bottle of trazodone contained sildenafil tablets.</p> <p>Sildenafil is indicated for the treatment of erectile dysfunction. Trazodone is indicated for the treatment of major depressive disorder in adults.</p>

## Key guideline/literature updates

Topic	Reference
Managing Asthma in Adolescents and Adults: 2020 Asthma Guideline Update - National Asthma Education and Prevention Program	<a href="#"><i>Journal of the American Medical Association</i></a> . December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Version 2.2021	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma</i></a> . December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 1.2021	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer</i></a> . December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 5.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers</i></a> . December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 4.2020	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer</i></a> . December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma - Version 1.2021	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma</i></a> . December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma - Version 1.2021	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma</i></a> . December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 4.2021	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma</i></a> . December 2020

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes - Version 2.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes.</u></a> December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 2.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u></a> December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u></a> December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas.</u></a> December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Lung Cancer Screening - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening.</u></a> December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Antiemesis.</u></a> December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue.</u></a> December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Palliative Care - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Palliative Care.</u></a> December 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation - Version 2.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</u></a> December 2020



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