

## New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Alkindi® Sprinkle</b> <sup>†</sup> (hydrocortisone) Eton Pharmaceuticals	Corticosteroid	Replacement therapy in pediatric patients with adrenocortical insufficiency	4 <sup>th</sup> quarter of 2020
<b>Gavreto®</b> (pralsetinib) <sup>†*</sup> Roche, Blueprint Medicines	RET inhibitor	Treatment of adult patients with metastatic rearranged during transfection fusion-positive non-small cell lung cancer as detected by an FDA approved test	September 9, 2020
<b>Qdolo®</b> (tramadol) oral solution Athena Biosciences	Opioid receptor agonist	In adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	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
<b>Bethkis</b> <sup>®</sup> (tobramycin) Chiesi	Teva <sup>†</sup>	300 mg/4 mL inhalation solution	Cystic fibrosis	September 16, 2020
<b>Ferriprox</b> <sup>®</sup> (deferiprone) Chiesi	Taro <sup>†</sup>	500 mg tablets	Transfusional iron overload due to thalassemia syndromes	September 18, 2020
<b>Tykerb</b> <sup>®</sup> (lapatinib) Novartis	Lupin <sup>†</sup>	250 mg tablets	Breast cancer	September 30, 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
<b>Bethkis</b> <sup>®</sup> (tobramycin) Chiesi	Prasco	300 mg/4 mL inhalation solution	Cystic fibrosis	September 16, 2020
<b>Zorvolex</b> <sup>®</sup> (diclofenac) Iroko	TriVue Pharmaceuticals	18 mg and 35 mg capsules	Mild to moderate acute pain and osteoarthritis pain	September 16, 2020

## Indications/label updates

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Drug name Manufacturer(s)	Type	Description
<b>Eraxis</b> <sup>®</sup> (anidulafungin) Pfizer	Expanded indication	Treatment of candidemia and certain <i>Candida</i> infections adults and pediatric patients 1 month of age and older
<b>Fetroja</b> <sup>®</sup> (cefiderocol) Shionogi	New indication	In patients 18 years of age or older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by the following susceptible Gram-negative microorganisms: <i>Acinetobacter baumannii</i> complex, <i>Escherichia coli</i> , <i>Enterobacter cloacae</i> complex, <i>Klebsiella pneumoniae</i> , <i>Pseudomonas aeruginosa</i> , and <i>Serratia marcescens</i>
<b>Haegarda</b> <sup>®</sup> (C1 esterase inhibitor [human]) CSL Behring	Expanded indication	Routine prophylaxis to prevent hereditary angioedema attacks in patients 6 years of age and older
<b>Kalydeco</b> <sup>®</sup> (ivacaftor) Vertex	Expanded indication	Treatment of cystic fibrosis in patients age 4 months and older who have one mutation in the cystic fibrosis transmembrane conductance regulator gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data
<b>Nucala</b> <sup>®</sup> (mepolizumab) GlaxoSmithKline	New indication	Treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome for ≥ 6 months without an identifiable non-hematologic secondary cause
<b>Simponi Aria</b> <sup>®</sup> (golimumab) Janssen	New and expanded indications	Treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older and for the treatment of active psoriatic arthritis in patients 2 years of age and older
<b>Trelegy Ellipta</b> <sup>®</sup> (fluticasone furoate/umeclidinium/vilanterol) GlaxoSmithKline	New indication	Maintenance treatment of asthma in patients aged 18 years and older
<b>Xeljanz</b> <sup>®</sup> (tofacitinib) Pfizer	New indication and new formulation	Treatment of active polyarticular course juvenile idiopathic arthritis in patients 2 years of age and older To support the new indication, a Xeljanz 1 mg/mL oral solution will be available by the end of the first quarter of 2021.

## Drug safety news

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Drug name Manufacturer(s)	Description
<b>Benzodiazepine Drug Class</b>	The FDA announced that the <i>Boxed Warning</i> will be updated for all benzodiazepine medicines to address the serious risks of abuse, addiction, physical dependence, and withdrawal reactions.

## Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
<b>NP Thyroid®</b> (thyroid) Acella Pharmaceuticals	$\frac{1}{4}$ grain (15 mg), 2 grain (120 mg) tablets	Recall	<p>Acella Pharmaceuticals announced a voluntary, consumer-level recall of one lot of 15 mg and one lot of 120 mg NP Thyroid tablets because testing has found these lots to be sub potent.</p> <p>NP Thyroid tablets are indicated as replacement or supplemental therapy in patients with hypothyroidism, in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's), multinodular goiter, and in the management of thyroid cancer.</p>
<b>Riomet ER™</b> (metformin) Sun Pharmaceuticals	500 mg per 5 mL extended-release oral suspension	Recall	<p>Sun Pharmaceuticals announced a voluntary, consumer-level recall of one lot of Riomet ER oral suspension due to the level of N-Nitrosodimethylamine (NDMA), which has been found to be above the allowable Acceptable Daily Intake limit established by the FDA.</p> <p>Riomet ER is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus.</p>

## Key guideline/literature updates

Topic	Reference
American College of Cardiology - Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients with Type 2 Diabetes	<a href="#"><u>Journal of the American College of Cardiology</u></a> . September 2020
American Gastroenterological Association - Gastrointestinal Evaluation of Iron Deficiency Anemia	<a href="#"><u>Gastroenterology</u></a> . August 2020
American Society of Hematology - Newly Diagnosed Acute Myeloid Leukemia in Older Adults	<a href="#"><u>Blood Advances</u></a> . August 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia - Version 4.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</u></a> . September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 6.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</u></a> . September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers - Version 3.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers</u></a> . September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma</u></a> . September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cutaneous Melanoma - Version 4.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Cutaneous Melanoma</u></a> .

	September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia.</u></a> September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 2.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u></a> September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes.</u></a> September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 8.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u></a> September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia.</u></a> September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma.</u></a> September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis.</u></a> September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uveal Melanoma - Version 2.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Uveal Melanoma.</u></a> September 2020

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma.</u></a> September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis - Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis.</u></a> September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic.</u></a> September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Distress Management.</u></a> September 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology - Version 1.2021	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology.</u></a> September 2020



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