

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Artesunate⁺ Amivas	Antimalarial	Initial treatment of severe malaria in adult and pediatric patients	TBD
Darzalex Faspro[™] (daratumumab and hyaluronidase-fihj) Janssen	Humanized anti-CD38 monoclonal antibody	Treatment of adult patients with multiple myeloma: in combination with Velcade [®] (bortezomib), melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant; in combination with Revlimid [®] (lenalidomide) and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy; in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent	May 4, 2020
Elyxyb[™] (celecoxib) oral solution Dr. Reddy's	Nonsteroidal anti-inflammatory drug	Acute treatment of migraine with or without aura in adults	TBD

Fensolvi [®] (leuprolide acetate) Tolmar Pharmaceuticals	Gonadotropin releasing hormone agonist	Treatment of pediatric patients 2 years of age and older with central precocious puberty	May 5, 2020
Ferriprox [®] (deferiprone) twice-a-day 1000 mg oral tablets Chiesi Global Rare Diseases	Iron chelator	Treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate	TBD
Impeklo [™] (clobetasol propionate) Mylan	Corticosteroid	Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years of age or older	TBD
Kynmobi [™] (apomorphine) Sunovion Pharmaceuticals	Non-ergoline dopamine agonist	Acute, intermittent treatment of “off” episodes in patients with Parkinson’s disease	September 2020
Phexxi [™] (lactic acid/citric acid/potassium bitartrate)* Evoform	Spermicidal agent	Prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception	September 2020
Oriahnn [™] (elagolix/estradiol/norethindrone acetate; elagolix) AbbVie	Gonadotropin-releasing hormone receptor antagonist/estrogen/progestin	Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	June 3, 2020
Qinlock [™] (ripretinib) [†] Deciphera Pharmaceuticals	PDGFR-alpha kinase inhibitor	Treatment of adult patients with advanced gastrointestinal stromal tumor who have received prior treatment with 3 or more kinase inhibitors, including imatinib (eg, Gleevec [®]).	May 19, 2020

<p>Retevmo™ (selpercatinib)^{†*} Eli Lilly</p>	<p>RET inhibitor</p>	<p>Treatment of: adult patients with metastatic RET fusion-positive non-small cell lung cancer; adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer who require systemic therapy; adult and pediatric 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 (if radioactive iodine is appropriate)</p>	<p>May 11, 2020</p>
<p>Tabrecta™ (capmatinib)^{†*} Novartis</p>	<p>cMET inhibitor</p>	<p>Treatment of adult patients with metastatic non-small cell lung cancer whose tumors have a mutation that leads to mesenchymal-epithelial transition exon 14 skipping as detected by an FDA-approved test</p>	<p>May 10, 2020</p>
<p>VESicare LS™ (solifenacin succinate) oral suspension Astellas</p>	<p>Muscarinic antagonist</p>	<p>Treatment of neurogenic detrusor overactivity in pediatric patients aged 2 years and older</p>	<p>Late 2020</p>
<p>Zilxi™ (minocycline) topical foam Menlo Therapeutics</p>	<p>Tetracyclines</p>	<p>Treatment of inflammatory lesions of rosacea in adults</p>	<p>Fourth quarter of 2020</p>

*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
Samsca [®] (tolvaptan) Otsuka	Alkem/Ascend [†]	30 mg tablets	Hypervolemic and euvolemic hyponatremia, including patients with heart failure and syndrome of inappropriate antidiuretic hormone	May 20, 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
Aptensio XR [™] (methylphenidate) Rhodes Pharmaceuticals	Rhodes Pharmaceuticals	10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg extended-release capsules	Attention deficit hyperactivity disorder	May 5, 2020
Samsca [®] (tolvaptan) Otsuka	Apotex	30 mg tablets	Hypervolemic and euvolemic hyponatremia, including patients with heart failure and syndrome of inappropriate antidiuretic hormone	May 20, 2020

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Alunbrig [®] (brigatinib) Takeda	Expanded indication	Treatment of adult patients with anaplastic lymphoma kinase positive metastatic non-small cell lung cancer
Brilinta [®] (ticagrelor) AstraZeneca	New indication	To reduce the risk of a first myocardial infarction or stroke in patients with coronary artery disease at high risk for such events
Cyramza [®] (ramucirumab) Eli Lilly	Expanded indication	In combination with erlotinib, for the first-line treatment of patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 substitution mutations
Dupixent [®] (dupilumab) Regeneron and Sanofi	Expanded indication	Treatment of patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
Farxiga [®] (dapagliflozin) AstraZeneca	New indication	Reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (New York Heart Association class II-IV) with reduced ejection fraction
Lynparza [®] (olaparib) AstraZeneca and Merck	New indication	Treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer who have progressed following prior treatment with Xtandi [®] (enzalutamide) or abiraterone
Opdivo [®] (nivolumab) and Yervoy [®] (ipilimumab) Bristol Myers Squibb	New indications	As first-line treatment in combination with Yervoy in adult patients with metastatic non-small cell lung cancer expressing PD-L1 ($\geq 1\%$) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations Opdivo, in combination with Yervoy and 2 cycles of platinum-doublet chemotherapy, for the first-line treatment of adult patients with metastatic or recurrent non-small cell lung cancer, with no EGFR or ALK genomic tumor aberrations
Pomalyst [®] (pomalidomide) Bristol Myers Squibb	New orphan indication	Treatment of adults with acquired immunodeficiency syndrome -related Kaposi sarcoma after failure of highly active antiretroviral therapy and Kaposi sarcoma in adult patients who are human immunodeficiency virus-negative

Rubraca [®] (rucaparib) Clovis Oncology	New indication	Treatment of adults with a deleterious BRCA mutation (germline and/or somatic) associated metastatic castration-resistant prostate cancer who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy
Sirturo [®] (bedaquiline) Janssen	Expanded indication	As part of combination therapy in the treatment of adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB)
Tecentriq [®] (atezolizumab) Genentech	Expanded indication	As a single agent, for the first-line treatment of adult patients with metastatic non-small cell lung cancer whose tumors have high PD-L1 expression (PD-L1 stained $\geq 50\%$ of tumor cells [TC $\geq 50\%$] or PD-L1 stained tumor-infiltrating immune cells [IC] covering $\geq 10\%$ of the tumor area [IC $\geq 10\%$]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations
Tecentriq [®] (atezolizumab) and Avastin [®] (bevacizumab) Genentech	New indication	In combination with bevacizumab (eg, Avastin [®]), is indicated for the treatment of patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy

Drug safety news

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Drug name Manufacturer(s)	Description
Metformin Extended-Release Products	<p>The FDA announced that laboratory testing has revealed levels of N-Nitrosodimethylamine (NDMA) above the agency's acceptable intake limit in several lots of the extended-release formulation of metformin.</p> <p>The FDA is in contact with five firms to recommend they voluntarily recall their products. Company recall notices will be posted on FDA's website. There are additional manufacturers of the metformin ER formulation that supply a significant portion of the U.S. market, and their products are not being recalled. FDA testing has not shown NDMA in immediate release metformin products.</p>

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Lactated Ringer's injection ICU Medical	1000 mL flexible container	Recall	ICU Medical announced a voluntary, consumer-level recall of one lot of Lactated Ringer's injection due to the presence of particulate matter identified as iron oxide. Lactated Ringer's injection is indicated for parenteral replacement of extracellular losses of fluid and electrolytes.
NP Thyroid® (thyroid tablets) Acella Pharmaceuticals	30 mg, 60 mg, and 90 mg tablets	Recall	Acella announced a consumer-level recall of thirteen lots of NP Thyroid because testing has found the recalled lots to be superpotent. The product may have up to 115.0% of the labeled amount of liothyronine. NP Thyroid is used to treat hypothyroidism.

Key guideline/literature updates

Topic	Reference
Eosinophilic Esophagitis Management - American Gastroenterological Association Institute and the American Academy of Allergy, Asthma & Immunology/American College of Allergy, Asthma & Immunology	<i>Gastroenterology</i> . May 2020
Ménière's Disease Executive Summary - American Academy of Otolaryngology - Head and Neck Surgery Foundation	<i>Otolaryngology – Head and Neck Surgery</i> . April 2020

Sickle Cell Disease: Prevention, Diagnosis, and Treatment of Cerebrovascular Disease in Children and Adults – American Society of Hematology	<i>Blood Advances</i> . April 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma - Version 2.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma</i> . May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 5.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</i> . May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 4.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</i> . May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 3.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer</i> . May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cutaneous Melanoma - Version 3.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Cutaneous Melanoma</i> . May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 2.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers</i> . May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 2.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer</i> . May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia - Version 2.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia</i> . May 2020

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 4.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms - Version 1.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 5.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary - Version 3.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Occult Primary.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer - Version 2.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 4.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma - Version 2.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma - Version 2.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis - Version 1.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis.</u> May 2020

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Testicular Cancer - Version 3.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uveal Melanoma - Version 1.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Uveal Melanoma.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction - Version 1.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue - Version 2.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue.</u> May 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation - Version 1.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</u> May 2020



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RxHighlights is published by the OptumRx Clinical Services Department.

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