

New drugs

| Drug name Manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|--|---|---|------------------------------|
| Anjeso™ (meloxicam) single dose vial Baudax Bio | Nonsteroidal anti-inflammatory drug (NSAID) | In adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics | Late April or early May 2020 |
| ArmonAir® Digihaler™ (fluticasone propionate) dry powder inhaler with an electric module Teva | Corticosteroid | Maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older | TBD |
| Audenz™ (influenza A [H5N1] monovalent vaccine, adjuvanted) Seqirus | Vaccine | For active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine. Audenz is approved for use in persons 6 months of age and older at increased risk of exposure to the influenza A H5N1 virus subtype contained in the vaccine. | TBD |
| Barhemsys® (amisulpride)* Acacia Pharma | Dopamine receptor antagonist | In adults for the prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class and for the treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis | Second half 2020 |
| Fluad® Quadrivalent (influenza vaccine, adjuvanted) Seqirus | Vaccine | Active immunization against influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. Fluad Quadrivalent is approved for use in persons 65 years of age and older. | TBD |

| Drug name Manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|---|--|---|--------------------|
| Nexleto™ (bempedoic acid)* Esperion | ATP-citrate lyase inhibitor | As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of low-density lipoprotein cholesterol (LDL-C) | March 30, 2020 |
| Nexlizet™ (bempedoic acid/ezetimibe)* Esperion | ATP citrate lyase/ cholesterol absorption inhibitor | As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering (LDL-C) | July 2020 |
| Nurtec™ ODT (rimegepant)* Biohaven Pharmaceuticals | Calcitonin gene-related peptide (CGRP) receptor antagonist | Acute treatment of migraine with or without aura in adults | March 3, 2020 |
| Pataday® Once Daily Relief (olopatadine) [±] Alcon | H1 histamine receptor antagonist | Temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair and dander, | March 2, 2020 |
| Pataday® Twice Daily Relief (olopatadine) [±] Alcon | H1 histamine receptor antagonist | Temporary relief of itchy and red eyes due to pollen, ragweed, grass, animal hair and dander | March 2, 2020 |

| Drug name Manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|---|------------------------------------|---|--------------------|
| Pemfexy™ (pemetrexed) single dose vial Eagle Pharmaceuticals | Folate analog metabolic inhibitor | <p>In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, nonsquamous, non-small cell lung cancer (NSCLC); as a single agent for the maintenance treatment of patients with locally advanced or metastatic nonsquamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy; as a single agent for the treatment of patients with recurrent, metastatic non-squamous NSCLC after prior chemotherapy</p> <p>In combination with cisplatin for the initial treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery</p> | TBD |
| Pizensy™ (lactitol)* Braintree Laboratories | Osmotic laxative | Chronic idiopathic constipation in adults | TBD |
| Procysbi® (cysteamine bitartrate) [†] delayed-release oral granules Horizon Therapeutics | Cystine-depleting agent | Treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older | First half of 2020 |
| Twirla® (levonorgestrel/ethinyl estradiol) Agile Therapeutics | Hormonal combination contraceptive | As a method of contraception for use in women of reproductive potential with a body mass index (BMI) < 30 kg/m ² for whom a combined hormonal contraceptive is appropriate | 4Q2020 |
| Voltaren® Arthritis Pain (diclofenac) [‡] GlaxoSmithKline | NSAID | Temporary relief of arthritis pain only in the following areas: hand, wrist, elbow (upper body areas) and foot, ankle, knee (lower body areas) | Spring 2020 |
| Vyepti™ (eptinezumab-jjmr)* Lundbeck | CGRP receptor antagonist | Preventive treatment of migraine in adults | April 2020 |

| Drug name Manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|--|-----------------------------------|---|--------------------|
| Xeljanz™ XR (tofacitinib) 22 mg extended-release tablet Pfizer | Janus associated kinase inhibitor | Treatment of adult patients with moderately to severely active ulcerative colitis who have an inadequate response or who are intolerant to tumor necrosis factor blockers | January 14, 2020 |

*New molecular entity †Orphan Drug ±New over-the-counter approval TBD: To be determined

New generics

[Learn more](#)

| Drug name Manufacturer(s) | Generic manufacturer(s) | Strength(s) & dosage form(s) | Therapeutic use | Launch information |
|--|-------------------------|--|--|--------------------|
| Moxeza® (moxifloxacin) Alcon | Lupin† | 0.5% ophthalmic solution | Bacterial conjunctivitis | February 14, 2020 |
| ProAir® HFA (albuterol) Teva | Perrigo† | Inhalation aerosol: 90 mcg per actuation | Bronchospasm in patients with reversible obstructive airway disease; and exercise-induced bronchospasm | February 25, 2020 |
| Vimovo® (naproxen/esomeprazole magnesium) Nuvo | Dr. Reddy's† | esomeprazole/naproxen: 20 mg/375 mg and 20 mg/500 mg delayed-release tablets | Symptomatic relief of arthritis and to decrease the risk for developing naproxen-associated gastric ulcers | February 27, 2020 |

†A-rated generic manufacturer

Indications/label updates

[Learn more](#)

| Drug name Manufacturer(s) | Type | Description |
|---|----------------|--|
| Nerlynx® (neratinib) Puma Biotechnology | New indication | In combination with capecitabine for the treatment of adults with advanced or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting |

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|--|-----------------------|--|
| <p>Trulicity® (dulaglutide) Eli Lilly</p> | <p>New indication</p> | <p>To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established CV disease or multiple CV risk factors</p> |
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Drug safety news

[Learn more](#)

| <p>Drug name Manufacturer(s)</p> | <p>Description</p> |
|---|--|
| <p>Metformin</p> | <p>The FDA announced that they posted laboratory results showing N-Nitrosodimethylamine (NDMA) levels in some metformin products approved in the U.S. They have determined that the levels of NDMA in metformin products tested range from not detectable to low levels. The FDA has not recommended metformin recalls to date.</p> <p>Metformin is used to control high blood sugar in patients with type 2 diabetes.</p> |

Drug recalls/withdrawals/shortages/discontinuations

| <p>Drug name Manufacturer(s)</p> | <p>Dosage form(s)</p> | <p>Type</p> | <p>Description</p> |
|---|--|--------------------|--|
| <p>Belviq®, Belviq XR (lorcaserin) Eisai</p> | <p>10 mg tablet; 20 mg extended-release tablet</p> | <p>Withdrawal</p> | <p>The FDA announced the request to voluntarily withdraw Belviq, Belviq XR from the U.S. market because a safety clinical trial showed an increased occurrence of cancer. Eisai, the manufacturer, has submitted a request to voluntarily withdraw the drug.</p> |
| <p>MiniMed™ 600 Series Insulin Pumps Medtronic</p> | <p>630G (MMT-1715) and 670G (MMT-1780) Insulin Pumps</p> | <p>Recall</p> | <p>The FDA announced a Class I recall of MiniMed 600 Series Insulin Pumps due to a missing or broken retainer ring which helps to lock the insulin cartridge into place in the pump's reservoir compartment. If the cartridge is not locked firmly into place, under or over delivery of insulin may occur, which could result in hypoglycemia or hyperglycemia.</p> |

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| <p>Phenytoin Taro Pharmaceuticals</p> | <p>125 mg/5 mL oral suspension</p> | <p>Recall</p> | <p>Taro Pharmaceuticals announced a voluntary, consumer-level recall of two lots of phenytoin oral suspension because product may not re-suspend when shaken, as instructed for administration, which could result in under or overdosing.</p> |
| <p>Ranitidine American Health Packaging</p> | <p>150 mg tablets</p> | <p>Recall</p> | <p>American Health Packaging announced a voluntary, consumer-level recall of prescription ranitidine tablets because of the potential presence of N-nitrosodimethylamine (NDMA) levels above the acceptable daily intake levels established by the FDA.</p> <p>Prescription ranitidine is used as a short-term treatment for active duodenal ulcers, maintenance therapy for duodenal ulcer patients, treatment of pathological hypersecretory conditions, short-term treatment of active, benign gastric ulcers, maintenance therapy for gastric ulcers, treatment of gastroesophageal reflux disease, and treatment of endoscopically diagnosed erosive esophagitis.</p> |

Key guideline/literature updates

| <p>Topic</p> | <p>Reference</p> |
|---|--|
| <p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: AIDS-Related Kaposi Sarcoma - Version 1.2020</p> | <p><i><u>NCCN Clinical Practice Guidelines in Oncology: AIDS-Related Kaposi Sarcoma.</u></i> February 2020</p> |
| <p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 2.2020</p> | <p><i><u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer.</u></i> February 2020</p> |
| <p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers - Version 1.2020</p> | <p><i><u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers.</u></i> February 2020</p> |

| Topic | Reference |
|---|--|
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes - Version 2.2020 | <u>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes.</u> February 2020 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 3.2020 | <u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> February 2020 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 3.2020 | <u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u> February 2020 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma - Version 6.2019 | <u>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</u> February 2020 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis - Version 1.2020 | <u>NCCN Clinical Practice Guidelines in Oncology: Antiemesis.</u> February 2020 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue - Version 1.2020 | <u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue.</u> February 2020 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Palliative Care - Version 1.2020 | <u>NCCN Clinical Practice Guidelines in Oncology: Palliative Care.</u> February 2020 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer in People Living with HIV - Version 1.2020 | <u>NCCN Clinical Practice Guidelines in Oncology: Cancer in People Living with HIV.</u> February 2020 |

| Topic | Reference |
|---|--|
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Older Adult Oncology - Version 1.2020 | <i>NCCN Clinical Practice Guidelines in Oncology: Older Adult Oncology.</i> February 2020 |



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