

New drugs

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| Drug name Manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|---|--|---|--------------------|
| Camcevi® (leuprolide) Forsee | Gonadotropin-releasing hormone analog | Treatment of adult patients with advanced prostate cancer | TBD |
| Empaveli™ (pegcetacoplan) ^{†*} Apellis | Complement C3 inhibitor | Treatment of adult patients with paroxysmal nocturnal hemoglobinuria | May 18, 2021 |
| Lumakras™ (sotorasib) ^{†*} Amgen | KRAS inhibitor | Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer, as determined by an FDA-approved test, who have received at least one prior systemic therapy | May 28, 2021 |
| Myfembree® (relugolix/estradiol/norethindrone acetate) Myovant Sciences and Pfizer | Gonadotropin-releasing hormone (GnRH) receptor antagonist/ estrogen/ progestin | Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women | May 27, 2021 |
| Rybrevant™ (amivantamab-vmjw) [*] Johnson & Johnson | Bispecific EGF receptor-directed and MET receptor-directed antibody | Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy | May 24, 2021 |
| Sotrovimab[‡] GlaxoSmithKline/Vir Biotechnology | Monoclonal antibody | Treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms [about 88 pounds]) with positive results of direct severe acute respiratory symptom coronavirus 2 (SARS-CoV-2) viral | May 26, 2021 |

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|--|-------------------------|--|--------------------|
| | | testing and who are at high risk for progression to severe COVID-19, including hospitalization or death | |
| Truseltiq™ (infigratinib) ^{†*} BridgeBio Pharma | Kinase inhibitor | Treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 fusion or other rearrangement as detected by an FDA-approved test | May 28, 2021 |

*New molecular entity; † Orphan drug; ±Emergency use authorization approval; 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 |
|--|----------------------------|---------------------------------|--|--------------------|
| Miacalcin® (calcitonin salmon) Mylan | Leucadia ^{†¶} | 400 units/2 mL injection | Paget's disease of the bone, hypercalcemia, and postmenopausal osteoporosis | May 17, 2021 |
| Thiola® (tiopronin) Retrophin | Teva [†] | 100 mg tablets | Prevention of cystine stone formation in patients with severe homozygous cystinuria who are not responsive to other measures | May 17, 2021 |

[†]A-rated generic manufacturer
[¶]Granted 180 days of marketing exclusivity

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New authorized brand alternatives

| Drug name Manufacturer(s) | Generic manufacturer(s) | Strength(s) & dosage form(s) | Therapeutic use | Launch information |
|--|-------------------------|------------------------------------|---|--------------------|
| Brovana® (arformoterol) Sunovion | Lupin | 15 mcg/2 mL inhalation solution | Maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema | May 26, 2021 |

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Indications/Label updates

| Drug name Manufacturer(s) | Type | Description |
|--|--|--|
| Cosentyx® (secukinumab) Novartis | Expanded indication | Treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy |
| COVID-19 Vaccine Pfizer | Expansion of emergency use authorization | The FDA approved an expansion to the Emergency Use Authorization for the coronavirus disease 2019 vaccine produced by Pfizer/BioNTech to include adolescents age 12 – 15 years |
| Ferriprox® (deferiprone) Chiesi Global Rare Diseases | New indication, expanded indication | Treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with thalassemia syndromes or with sickle cell disease or other anemias |
| Keytruda® (pembrolizumab) Merck | Expanded indication | In combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma |
| Noxafil® PowderMix, Noxafil® (posaconazole) Merck | Expanded indication, new formulation | Prophylaxis of invasive <i>Aspergillus</i> and <i>Candida</i> infections in pediatric patients 2 years of age and older who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant recipients with graft-versus-host disease or those with hematologic malignancies with prolonged neutropenia from chemotherapy Noxafil PowderMix, a delayed release oral suspension was also approved. |

| Drug name Manufacturer(s) | Type | Description |
|--|---------------------|---|
| Nurtec® ODT (rimegepant) Biohaven | New indication | Preventive treatment of episodic migraine in adults |
| Opdivo® (nivolumab) Bristol Myers Squibb | Expanded indication | Adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in patients who have received neoadjuvant chemoradiotherapy |
| Yervoy® (ipilimumab) Bristol Myers Squibb | Expanded indication | In combination with Opdivo, for the treatment of unresectable or metastatic melanoma in adult patients |
| Zeposia® (ozanimod) Bristol Myers Squibb | New indication | Treatment of moderately to severely active ulcerative colitis in adults |
| Zipsor® (diclofenac potassium) capsule Assertio Therapeutics | Expanded indication | For relief of mild to moderate acute pain in adult and pediatric patients 12 years of age and older |

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Drug safety news

| Drug name Manufacturer(s) | Description |
|---|--|
| Ocaliva® (obeticholic acid) Intercept | A new <i>Contraindication</i> will be added to the Ocaliva drug label stating that it should not be used in primary biliary cholangitis patients with advanced cirrhosis. The <i>Boxed Warning</i> will also be revised to include this information along with related warnings about this risk. |

Key guideline/Literature updates

| Topic | Reference |
|--|--|
| American College of Physicians - Appropriate Use of Short-Course Antibiotics in Common Infections | <i>Annals of Internal Medicine</i> . April 2021 |
| American Thyroid Association - Management of Patients with Anaplastic Thyroid Cancer | <i>Thyroid</i> . March 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 4.2021 | <i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i> . May 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis - Version 1.2021 | <i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis</i> . May 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal - Version 1.2021 | <i>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal</i> . May 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors - Version 4.2021 | <i>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors</i> . May 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities - Version 3.2021 | <i>NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities</i> . May 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Older Adult Oncology - Version 1.2021 | <i>NCCN Clinical Practice Guidelines in Oncology: Older Adult Oncology</i> . May 2021 |



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