

New drugs

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| Drug name Manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|--------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Cabenuva™ (cabotegravir, rilpivirine)* ViiV Healthcare | HIV integrase inhibitor/ non-nucleoside reverse transcriptase inhibitor | As a complete regimen for the treatment of human immunodeficiency virus type 1 infection in adults to replace the current antiretroviral (ARV) regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable ARV regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine | January 25, 2021 |
| Gamifant™ (emapalumab-lzsg) 100 mg/20 mL (5 mg/mL) solution in a single-dose vial† Novimmune, Sobi | Interferon gamma blocking antibody | Treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy | December 20, 2021 |
| Iclevia™ (levonorgestrel and ethinyl estradiol tablets) 91-day tablet pack Aurobindo | Contraception | For use by females of reproductive potential to prevent pregnancy | December 7, 2020 |
| Iclusig® (ponatinib) 10 mg and 30 mg tablets Takeda | Kinase inhibitor | Treatment of adult patients with chronic phase chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors; accelerated phase (AP) or blast phase CML or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are | January 18, 2021 |

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| | | indicated; and T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL. | |
| Vocabria™ (cabotegravir)* ViiV Healthcare | HIV integrase inhibitor | In combination with rilpivirine tablets, as a complete regimen for short-term treatment of HIV-1 infection in adults who are virologically stable and suppressed on a stable ARV regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine, for use as an oral lead-in to assess tolerability of cabotegravir prior to initiating Cabenuva and as an oral therapy for patients who will miss planned injection dosing of Cabenuva | February 1, 2021 |
| Lupkynis™ (voclosporin)* Aurinia Pharmaceuticals | Calcineurin inhibitor | In combination with a background immunosuppressive therapy regimen, for the treatment of adult patients with active lupus nephritis | January 26, 2021 |
| Verquvo™ (vericiguat)* Merck | Guanylate cyclase stimulator | To reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for HF or need for outpatient intravenous diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45% | January 24, 2021 |

*New molecular entity; †Orphan drug

New authorized brand alternatives

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| Drug name Manufacturer(s) | Generic manufacturer(s) | Strength(s) & dosage form(s) | Therapeutic use | Launch information |
|--------------------------------------------------|-------------------------|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Amitiza® (lubiprostone) Sucampo/Takeda | Par | 8 mcg and 24 mcg capsules | Chronic idiopathic constipation; opioid-induced constipation in adults with chronic non-cancer pain; and irritable bowel syndrome with constipation | January 4, 2021 |
| Zomig® (zolmitriptan) Amneal Specialty | Amneal | 2.5 mg and 5 mg nasal spray | Acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older | January 19, 2021 |

Indications/label updates

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| Drug name Manufacturer(s) | Type | Description |
|------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Darzalex Faspro [®] (daratumumab/hyaluronidase-fihj) Janssen | New indication, expanded indication | In combination with bortezomib, cyclophosphamide, and dexamethasone for the treatment of adult patients with newly diagnosed light chain amyloidosis. Darzalex Faspro is also approved as monotherapy and as part of various combination treatment regimens for the treatment of adult patients with multiple myeloma. |
| Edurant [®] (rilpivirine) Janssen | New indication | In combination with Vocabria for short-term treatment of HIV-1 infection in adults who are virologically stable and suppressed on a stable ARV regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine, for use as an oral lead-in to assess tolerability of rilpivirine extended-release suspension, a component of Cabenuva and as an oral therapy for patients who will miss planned injection dosing with Cabenuva extended-release injectable suspensions |
| Enhertu [®] (fam-trastuzumab deruxtecan-nxki) Daiichi Sankyo, AstraZeneca | New indication | Treatment of adult patients with locally advanced or metastatic human epidermal growth factor receptor 2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen |
| Fibryga [®] (fibrinogen [human]) Octapharma | Expanded indication | Treatment of acute bleeding episodes in adults and children with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia |
| Opdivo [®] (nivolumab) and Cabometyx [®] (cabozantinib) Bristol Myers Squibb, Exelixis | Expanded indication | First-line treatment of patients with advanced renal cell carcinoma |
| Xalkori [®] (crizotinib) Pfizer | New indication | Treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase-positive |

Drug recalls/withdrawals/shortages/discontinuations

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| Drug name Manufacturer(s) | Dosage form(s) | Type | Description |
|----------------------------------------------------------------|--------------------------|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cisatracurium injection Meitheal | 10 mg per 5 mL injection | Recall | <p>Meitheal announced a voluntary, user level recall of one lot of cisatracurium injection because a product complaint revealed that a portion of one lot of cartons labeled as cisatracurium injection 10 mg/5 mL, containing ten vials per carton, contained ten vials mis-labeled as phenylephrine hydrochloride injection 100 mg/10 mL.</p> <p>Cisatracurium injection is indicated as an adjunct to general anesthesia to facilitate tracheal intubation; to provide skeletal muscle relaxation during surgical procedures or during mechanical ventilation.</p> |
| Metformin extended-release (ER) Nostrum Laboratories | 750 mg ER tablets | Recall | <p>Nostrum announced a voluntary, consumer level recall of one lot of metformin 750 mg ER tablets due to contamination with n-nitrosodimethylamine (NDMA) above the acceptable daily intake (ADI) limit of 96 ng/day. This is an expansion of the recall initially announced on November 2, 2020.</p> <p>Metformin is indicated as an adjunct to diet and exercise to improve glycemic control in patients type 2 diabetes mellitus.</p> |
| Paroex® (chlorhexidine gluconate) Precision Dose | 0.12% oral rinse | Recall | <p>Precision Dose announced a voluntary, consumer level recall of Paroex (chlorhexidine gluconate) 0.12% oral rinse, labeled with expiration dates of 1/31/21 – 2/28/22, due to contamination with Burkholderia lata.</p> <p>Chlorhexidine gluconate is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing.</p> |

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| <p>Spirolactone BRP</p> | <p>25 mg and 50 mg tablets</p> | <p>Recall</p> | <p>BRP announced a voluntary, consumer level recall of four lots of spironolactone tablets due to potential mislabeled package displaying incorrect strength information.</p> <p>Spirolactone tablets are indicated for the treatment of heart failure, hypertension, edema associated with hepatic cirrhosis or nephrotic syndrome, and primary hyperaldosteronism.</p> |
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Key guideline/literature updates

| Topic | Reference |
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| <p>Hypertrophic Cardiomyopathy – American Heart Association and American College of Cardiology</p> | <p><i>Journal of the American College of Cardiology.</i> December 2020.</p> |
| <p>Gonococcal Infection - Centers for Disease Control and Prevention</p> | <p><i>Morbidity and Mortality Weekly Report.</i> December 2020.</p> |
| <p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 1.2021</p> | <p><i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas.</i> January 2021</p> |
| <p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 1.2021</p> | <p><i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer.</i> January 2021</p> |
| <p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia - Version 3.2021</p> | <p><i>NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia.</i> January 2021</p> |

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| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 2.2021 | <u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer.</u> January 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma - Version 2.2021 | <u>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma.</u> January 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes - Version 3.2021 | <u>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes.</u> January 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer - Version 2.2020 | <u>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.</u> January 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Penile Cancer - Version 1.2021 | <u>NCCN Clinical Practice Guidelines in Oncology: Penile Cancer.</u> January 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 2.2021 | <u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u> January 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uveal Melanoma - Version 3.2020 | <u>NCCN Clinical Practice Guidelines in Oncology: Uveal Melanoma.</u> January 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection - Version 1.2021 | <u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u> January 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management - Version 2.2021 | <u>NCCN Clinical Practice Guidelines in Oncology: Distress Management.</u> January 2021 |

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| <p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation - Version 1.2021</p> | <p><u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation.</u> January 2021</p> |
| <p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer in People with HIV - Version 1.2021</p> | <p><u>NCCN Clinical Practice Guidelines in Oncology: Cancer in People with HIV.</u> January 2021</p> |



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