

RxHighlights

February 2022

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New drugs

| Drug name manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|--|---|--|--------------------|
| Aspruzo Sprinkle™ (ranolazine) Sun Pharma | Antianginal | Treatment of chronic angina | TBD |
| Carvykti™ (ciltacabtagene autoleucel) ^{†*} Janssen | CAR T cell therapy | Treatment of adult patients with relapsed or refractory multiple myeloma, after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody | March 3, 2022 |
| Enjaymo™ (sutimlimab-jome) ^{†*} Sanofi | Complement C1s subcomponent inhibitor | To decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease | February 10, 2022 |
| Fleqsuvy™ (baclofen) oral suspension Azurity | Gamma-aminobutyric acid agonist | Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity | February 9, 2022 |
| Norliqva® (amlodipine) oral solution CMP Pharma | Calcium channel blocker | Treatment of hypertension, to lower blood pressure in adults and children 6 years of age and older; symptomatic treatment of chronic stable angina; confirmed or suspected vasospastic angina; patients with recently documented coronary artery disease by angiography and without heart failure or an ejection fraction < 40%, to reduce the risk of hospitalization for angina and to reduce the risk of a coronary revascularization procedure | TBD |
| Pyrukynd® (mitapivat) ^{†*} Agios | Pyruvate kinase activator | Treatment of hemolytic anemia in adults with pyruvate kinase deficiency | March 2, 2022 |

| Drug name manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|--|---|---|--------------------|
| Talzenna™ (talazoparib) 0.5 mg and 0.75 mg capsules Pfizer | Poly (ADP-ribose) polymerase (PARP) inhibitor | Treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene-mutated human epidermal growth factor receptor 2-negative locally advanced or metastatic breast cancer | January 31, 2022 |
| Vonjo™ (pacritinib) [†] CTI BioPharma | Janus associated kinase-2 inhibitor | Treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below $50 \times 10^9/L$ | March 9, 2022 |

*New molecular entity; † Orphan drug; TBD: To be determined

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New biosimilars

| Drug name manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|--|---------------------------------------|---|-----------------------|
| Releuko® (filgrastim-ayow) Amgen | Granulocyte-colony stimulating factor | <p>To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever</p> <p>For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia</p> <p>To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation</p> <p>For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis</p> <p>To reduce the incidence and duration of sequelae of neutropenia (eg, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia</p> | Third quarter of 2022 |

New generics

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| Drug name manufacturer(s) | Generic manufacturer(s) | Strength(s) & dosage form(s) | Therapeutic use | Launch information |
|---|-----------------------------------|---|---|--------------------|
| AmBisome [®] (amphotericin B) Astellas | Sun Pharmaceuticals ^{†±} | 50 mg liposome for injection | Fungal infection in febrile, neutropenic patients; Cryptococcal meningitis in HIV-infected patients; <i>Aspergillus</i> species, <i>Candida</i> species and/or <i>Cryptococcus</i> species infections; visceral leishmaniasis | February 15, 2022 |
| Revex [®] (nalmeфene hydrochloride) [‡] Baxter | Purdue [†] | 2 mg/2 mL single dose vial | Reversal of opioid drug effects, including respiratory depression, induced by either natural or synthetic opioids, and in the management of known or suspected opioid overdose | Mid-2022 |
| Restasis [®] (cyclosporine) Allergan | Viatrix [†] | 0.05% ophthalmic emulsion preservative-free single-use vial | Increase tear production due to ocular inflammation associated with keratoconjunctivitis sicca | February 3, 2022 |
| Selzentry [®] (maraviroc) ViiV Healthcare | Camber/Hetero [†] | 150 mg and 300 mg tablets | In combination with other antiretroviral agents for the treatment of only chemokine coreceptor 5-tropic human immunodeficiency virus type 1 infection in adult and pediatric patients weighing at least 2 kg | February 7, 2022 |

†A-rated generic manufacturer; ±Granted 180 days of marketing exclusivity; ‡Discontinued in 2008

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Indications/Label updates

| Drug name manufacturer(s) | Type | Description |
|--|--|--|
| Actemra [®] (tocilizumab) Genentech | Updated labeling | The FDA approved Genentech's intravenous formulation of Actemra, for treatment of giant cell arteritis in adult patients. Previously, only the subcutaneous formulation of Actemra was approved for this indication. |
| Bebtelovimab Eli Lilly | Emergency use authorization approval | Treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive results of SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate |
| Jardiance [®] (empagliflozin) Boehringer Ingelheim, Eli Lilly | Expanded indication | To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure |
| Xigduo [®] XR (dapagliflozin/metformin) AstraZeneca | New indication | To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction |

[Learn more](#)**Drug safety news / Drug updates**

| Drug name manufacturer(s) | Description |
|--|---|
| Spikevax™ (COVID-19 vaccine, mRNA) Moderna | The Center for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) met to discuss the FDA approval of Spikevax. ACIP voted unanimously in favor of vaccination with Spikevax COVID-19 vaccine (2-doses, 100 mcg, intramuscularly) for adults 18 years of age and older. |
| Ukoniq® (umbralisib) TG Therapeutics | The FDA is investigating a possible increased risk of death with Ukoniq, approved to treat marginal zone lymphoma and follicular lymphoma. Initial findings from a clinical trial evaluating Ukoniq to treat a related type of cancer found a possible increased risk of death in patients taking the medicine. |

[Learn more](#)**Drug recalls/Withdrawals/Shortages/Discontinuations**

| Drug name manufacturer(s) | Strength(s) and dosage form(s) | Type | Description |
|--|---|-----------------|---|
| Intron® A (interferon alfa-2b) Merck | 10 million IU/vial, 5 mL vial; 18 million IU/vial, 5 mL vial; 50 million IU/vial, 5 mL vial | Discontinuation | Merck announced the permanent discontinuation of Intron A due to business reasons. The discontinuation is not due to any safety, efficacy or quality reasons. Intron A powder for injection is expected to be discontinued on or near March 2022. Intron A solution for injection was discontinued June 2021 - July 2021. There are no other manufacturers that produce interferon alfa-2b. Intron A is indicated for the treatment of hairy cell leukemia, malignant melanoma, follicular lymphoma, condylomata acuminata, AIDS-related Kaposi's sarcoma, chronic hepatitis C, and chronic hepatitis B. |
| Lacrisert® (hydroxypropyl cellulose ophthalmic insert) Bausch | 5 mg ophthalmic insert | Shortage | The drug shortage of Lacrisert is ongoing. Bausch estimates supply will resume in July 2023. Lacrisert is indicated in patients with moderate to severe dry eye syndromes, including keratoconjunctivitis sicca. Lacrisert is indicated especially in patients who remain symptomatic after an adequate trial of therapy with artificial tear solutions. Lacrisert is also indicated for patients with exposure keratitis, decreased corneal sensitivity, and recurrent corneal erosions. |

| Drug name manufacturer(s) | Strength(s) and dosage form(s) | Type | Description |
|--|--|--------|---|
| Similac[®], Alimentum[®], EleCare[®] Abbott | Various sized packages of infant formula | Recall | The FDA announced a consumer-level recall of several lots of Similac, Alimentum and EleCare infant formulas after four consumer complaints related to <i>Cronobacter sakazakii</i> or <i>Salmonella</i> Newport in infants who had consumed powder infant formula manufactured at one of Abbott's facilities. |
| Sodium chloride injection B. Braun | 0.9% solution for injection, 250 mL flexible container | Recall | B. Braun announced a consumer-level recall of five lots of sodium chloride intravenous solution 0.9%, 250 mL due to the potential for leaks or low fill volume of the respective containers. Sodium chloride for injection is indicated for extracellular fluid replacement, treatment of metabolic alkalosis in the presence of fluid loss and mild sodium depletion; use as a priming solution for hemodialysis and may be used to initiate and terminate blood transfusions without hemolyzing red blood cells and as an aids and diluents for the infusion of drugs. |

Key guideline/Literature updates

| Topic | Reference |
|---|--|
| Advisory Committee on Immunization Practices - Recombinant Zoster Vaccine in Immunocompromised Adults | <u>Morbidity and Mortality Weekly Report</u> . January 2022 |
| Advisory Committee on Immunization Practices - 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine in Adults | <u>Morbidity and Mortality Weekly Report</u> . January 2022 |
| National Institutes of Health – COVID-19 Treatment | <u>COVID-19 Treatment Guidelines</u> . February 2022 |
| Joint Healthcare Infection Society and Infection Prevention Society – Prevention and Control of methicillin-resistant <i>Staphylococcus aureus</i> in healthcare facilities | <u>Journal of Hospital Infection</u> . October 2021 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 1.2022 | <u>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</u> . |

| Topic | Reference |
|--|---|
| | February 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Colon Cancer - Version 1.2022 | <u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer.</u> February 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 2.2022 | <u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</u> February 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma - Version 2.2022 | <u>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma.</u> February 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms - Version 1.2022 | <u>NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms.</u> February 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma - Version 1.2022 | <u>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma.</u> February 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 1.2022 | <u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u> February 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection - Version 1.2022 | <u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u> February 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities - Version 1.2022 | <u>NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities.</u> February 2022 |



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