# Approvals & Updates

January 2023

## New Drug Approvals

### Briumvi (ublituximab-xiiy)

**Indication:** Relapsing forms of multiple sclerosis (MS)

**Mechanism of Action:** CD20-directed cytolytic antibody

**Dosage Form(s):** Intravenous injection

**Comments:** Briumvi is FDA approved for treating adults with relapsing forms of MS (clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease). Screening for hepatitis B virus and quantitative serum immunoglobulin are required before starting Briumvi. Premedication with methylprednisolone (or equivalent corticosteroid) and an antihistamine prior to each infusion. Briumvi is administered via intravenous infusion (IV). The first infusion of Briumvi is administered as 150mg IV; the second infusion administered as 450mg IV two weeks after the first infusion; and subsequent infusions as 450mg IV 24 weeks after the first infusion and every 24 weeks thereafter. Briumvi must be diluted in 0.9% sodium chloride. Patients must be closely monitored during and for ≥1 hour after the first two infusions. Thereafter, physician discretion is advised for post-infusion monitoring of subsequent infusions. Briumvi has labeled contraindications for active hepatitis B virus infection and patients with a history of life-threatening infusion reactions to Briumvi. Briumvi has labeled warnings and precautions for infusion reactions, serious infections, reduction in immunoglobulins, and fetal risk. The most common adverse reactions reported (≥10%) with Briumvi are infusion reactions and upper respiratory tract infections.

### Krazati (adagrasib)

**Indication:** KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC)

**Mechanism of Action:** KRAS G12C inhibitor

**Dosage Form(s):** Oral tablets

**Comments:** Krazati is FDA-approved for treating adults with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) that has been detected by an FDA approved test and who have received ≥1 prior systemic therapy. Krazati 600mg tablets are swallowed whole and taken orally twice daily. Krazati has labeled warnings and precautions for gastrointestinal adverse reactions, QTc interval prolongation, hepatotoxicity, interstitial lung disease/pneumonitis. Several significant drug-drug interactions are associated with Krazati. Avoid the concomitant use of strong CYP3A4 inducers, inhibitors, and sensitive substrates, sensitive CYP2C9 or CYP2D6 substrates or P-gp substrates, and drugs that prolong the QT interval with Krazati. The most common Grade 3 or 5 laboratory abnormalities (≥2%) reported with Krazati are decreased (lymphocytes, hemoglobin, leukocytes, and neutrophils) and increased (alanine, aspartate, and alkaline phosphatase), hypokalemia, and hyponatremia. The most common adverse reactions (≥25%) reported with Krazati are nausea, diarrhea, vomiting, fatigue, musculoskeletal pain, hepatotoxicity, renal impairment, edema, dyspnea, and decreased appetite.

## Lunsumio (mosunetuzumab-axgb)

**Indication:** Relapsed or refractory follicular lymphoma

**Mechanism of Action:** Bispecific CD20-directed CD3 T-cell engager

**Dosage Form(s):** Intravenous injection

**Comments:** Lunsumio is FDA-approved for treating adults with relapsed or refractory follicular lymphoma after ≥2 lines of systemic therapy. Lunsumio is administered to well-hydrated patients and only as an intravenous infusion through a dedicated infusion line using a drip chamber filter. Only qualified healthcare professionals with appropriate medical support to manage severe reactions should administer Lunsumio. Premedication with a corticosteroid, antihistamine, and an antipyretic is required before each dose in Cycle 1 and Cycle 2. The recommend dosage of Lunsumio is Cycle 1 Day 1 (1mg), Cycle 1 Day 8 (2mg), Cycle 1 Day 15 (60mg), Cycle 2 Day 1 (60mg), Cycle 3+ Day 1 (30mg). Lunsumio has a boxed warning for cytokine release syndrome (CRS). Lunsumio has labeled warnings are precautions for neurologic toxicity, infections, cytopenias, tumor flares, and embryo-fetal toxicity. The most common grade 3 to 4 laboratory abnormalities (≥10%) reported with Lunsumio are decreased (lymphocyte count, phosphate, neutrophil count, white blood cell count, hemoglobin, and platelets), increased (glucose and uric acid). The most common adverse reactions (≥20%) reported with Lunsumio are CRS, fatigue, rash, pyrexia, and headache.

## Rezlidhia (olutasidenib)

**Indication:** Relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation

**Mechanism of Action:** Isocitrate dehydrogenase-1 (IDH1) inhibitor

**Dosage Form(s):** Oral capsules

**Comments:** Rezlidhia is FDA-approved for treating adults with refractory or relapsed acute myeloid leukemia (AML) with a susceptible IDH1 mutation that is detected by an FDA-approved test. Rezlidhia 150mg is taken orally twice daily on an empty stomach at least 1 hour before or 2 hours after a meal, until disease progression or unacceptably toxicity occurs. Rezlidhia has a boxed warning for differentiation syndrome. If differentiation syndrome occurs, Rezlidhia should be withheld, and corticosteroids and hemodynamic monitoring should be initiated. Rezlidhia has a labeled warning for hepatotoxicity, so monitoring of liver function tests should occur during treatment. Avoid the concomitant use of Rezlidhia with strong or moderate CYP3A4 inducers and sensitive CYP3A substrates. The most common adverse reactions (≥20%) reported with Rezlidhia are increased (aspartate, alanine, alkaline phosphatase, creatinine, lymphocytes, bilirubin, uric acid, and lipase), decreased (potassium, sodium), and nausea, fatigue/malaise, arthralgia, constipation, leukocytosis, dyspnea, pyrexia, rash, mucositis, diarrhea, and transaminitis.

## Sunlenca (lenacapavir)

**Indication:** Human immunodeficiency virus (HIV) infection

**Mechanism of Action:** Human immunodeficiency virus type 1 (HIV-1) capsid inhibitor

**Dosage Form(s):** Oral tablets, subcutaneous injection

**Comments:** Sunlenca when used in combination with other antiretrovirals is FDA-approved for treating heavily treated-experienced adults with HIV-1 infection, who are currently failing their antiretroviral regimen due to multidrug resistant HIV-1 infection, intolerance, or safety considerations. There are two initiation options for Sunlenca which is then followed by a once every 6-months maintenance dosing. Initiation option 1 is Sunlenca 927mg via subcutaneous injection (subQ) and 600mg orally on Day 1; followed by 600mg orally on Day 2. Initiation option 2 is Sunlenca 600mg orally on Day(s) 1 and 2; followed by 300mg orally on Day 8; then 927mg via subQ on Day 15. Sunlenca has a contraindication for the concomitant use with strong CYP3A inducers. Sunlenca has labeled warnings and precautions for immune reconstitution syndrome, residual concentrations of Sunlenca remaining in systemic circulation for up to 12 months or longer, increased exposure and risk of adverse reactions to drugs metabolized by CYP3A that was initiated within 9 months after the last subQ dose of Sunlenca, and initiation of an alternative, fully suppressive antiretroviral regimen no later than 28 weeks after the final injection of Sunlenca, and injection site reactions. The most common adverse reactions (≥3%) reported with Sunlenca are nausea and injection site reactions.

## Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Quinapril and HCTZ tablets
- Quinapril tablets

For additional information on drug shortages, please contact the Center for Drug Information & Evidence-Based Practice.

## Recently Approved Drug Combinations, Dosage Forms/Strengths, Indications, and Biosimilars

| Brand (Generic) | Indication | Mechanism of Action | Dosage Form | Comments |
|---|---|---|---|---|
| Idacio (adalimumab-aacf) | Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis | Tumor necrosis factor (TNF) blocker | Subcutaneous injection | Biosimilar to Humira |
| Nexobrid (anacaulase-bcdb) | Eschar removal of deep partial thickness and/or full thickness thermal burns | Proteolytic enzymes | Topical gel | New biologic product |
| Xenoview (xenon Xe 129 hyperpolarized) | Magnetic resonance imaging (MRI) for evaluation of lung ventilation | Hyperpolarized contrast agent | Oral inhalation | New contrast agent |

Creighton University Center for Drug Information & Evidence-Based Practice

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