Kroger Prescription Plans

Q2 Recent Drug Developments and Product Approvals

At Kroger Prescription Plans (KPP), we understand that staying ahead of drug development and market launch is key to successful drug spend management. By analyzing how future drug approvals will change the prescribing landscape, clients and payers can more easily anticipate future drug spend and take appropriate steps to ensure drug costs don't spiral out of control.

On a quarterly basis, KPP researches and analyzes new drug approvals with the goal of predicting how these products will disrupt the clinical status quo.

With the help of our in-house Pharmacy and Therapeutics committee, and our wholly owned specialty pharmacy, Kroger Specialty Pharmacy (KSP), our goal is to provide best-in-class clinical analytics for our clients. Our clinical team has summarized the key products that have recently come to market or are anticipated to launch in the coming months.

Hemgenix (etranacopene dezaparvovec)
by CSL Behring

Rezlidhia (olutasidenib)
by Rigel Pharmaceuticals

Rebyota (fecal microbiota, live-jslm)
by Ferring Pharmaceuticals

Krazati (adagrasib)
by Mirati Therapeutics

Lunsumio (mosunetuzumab-axgb)
by Roche/Genentech

Sunlenca (lenacapavir)
by Gilead Science

Briumvi (ublituximab-xiiy)
by TG Therapeutics

Legembi (lecanemab-irb)
by Eisai/Biogen

Jaypirca (pirtobrutibib)
by Eli Lily

Orserdu (elacestrant)
by Stemline Therapeutics

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Hemgenix (etranacopene dezaparvovec)
by CSL Behring

Hemgenix was approved on November 22, 2023 as the first FDA approved treatment for adults with hemophilia B (congenital factor IX [FIX] deficiency) who currently use FIX prophylaxis therapy; have current or historical life-threatening hemorrhage; or have repeated, serious spontaneous bleeding episodes. Hemophilia B is a rare genetic bleeding disorder that is caused from missing or insufficient levels of FIX. The HOPE-B trial showed positive data to support the approval of this drug and its use to treat Hemophilia B.

Rezlidhia (olutasidenib)
by Rigel Pharmaceuticals

Rezlidhia was approved on December 1, 2022, for the treatment adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation. There are about 20,000 new cases of AML reported each year making it one of the most common types of leukemia in adults. In approximately 6%-10% of the diagnosed AML cases, the IDH1 mutation is seen leading to poorer prognosis. Study 2102-HEM-101 was the trial that showed positive results leading to the approval of Rezlidhia.

Rebyota (fecal microbiota, live-jslm)
by Ferring Pharmaceuticals

Rebyota was approved for the prevention of recurrence of Clostridioides difficile infection in those who are at least 18 years old and on an antibiotic regiment for recurrent Clostridioides difficile infection on November 30, 2022. This drug is the first microbiome therapy approved by the FDA. Recurrent Clostridioides difficile infection happens in about 15%-30% of the 500,000 patients in the United States who get Clostridioides difficile infection. During the PUNCH-CD3 trial, 70.6% of the patients in the Rebyota group had successful treatment compared to the 57.5% in the placebo group, leading to the approval.

Krazati (adagrasib)
by Mirati Therapeutics

Krazati is an oral KRAS G12C inhibitor that was approved on December 12,2022 to treat adults with KRAS G12C mutated locally advanced or metastatic non–small cell lung cancer (NSCLC). This mutation occurs in about 14% of the mutations that occur in NSCLC which is about 7000 patients in the United States per year. Data from the KRYSTAL-1 trial led to the accelerated approved of Krazati and the ongoing trial KRSTAL-12 will confirm the findings. There is another drug, Lumakras (sotorasib) that Krazati will be competing with on the market as it was the first oral KRAS G12C inhibitor approved.

Lunsumio (mosunetuzumab-axgb)
by Roche/Genentech

An accelerated approval was granted on December 22, 2022 for Lunsumio which is used to treat adults with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy. Lunsumio is a bispecific CD20-directed CD3 T-cell engager and the first drug in its class to get approved for R/R FL. The GO29781 had 90 patients who had received two or mor prior therapies, showed an 80% objective response rate.

Sunlenca (lenacapavir)
by Gilead Science

The first drug in a new class of drugs called Sunlenca was approved on December 22, 2022 for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced (HTE) adults with multidrug-resistant (MDR) HIV1 infection failing their current ARV regimen due to resistance, intolerance, or safety considerations. Sunlenca blocks the HIV-1 virus capside which interferes with essential steps of the viral life cycle. This drug can help about 2% of the population living with HIV and who are on ARV treatments worldwide. During the Capella trial, 88% of the patients who were given Sunlenca reached the primary endpoint of the decrease in viral load compared to the placebo group where only 17% had the decrease in viral load after a 14 day functional monotherapy period. There was also a maintenance period where an optimized background regimen was given with the Sunlenca and 83% of the participants reached an undetectable viral load by week 52.

Briumvi (ublituximab-xiiy)
by TG Therapeutics

On December 28,2022 a new drug to treat adults with relapsing forms of multiple sclerosis (RMS) including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease called Briumvi was approved. ULTIMATE 1 and ULTIMATE 2 trials were conducted and had 1094 patients with RMS participate. Superiority over Aubagio was shown by Briumvi by significant reducing the annualized relapse rate and the number of magnetic resonance imaging detected brain lesions. This is the third antiC20 inhibitor approved for MS.

Legembi (lecanemab-irb)
by Eisai/Biogen

A second anti-amloid monoclonal antibody used for the treatment of Alzheimer's disease (AD), Leqembi, was approved on January 6, 2023. After 18 months, lowering of the accumulation of Aβ plaque in the brain was shown when treated with Leqembi in Study 201. When using Leqembi, it should be started in patients with mild cognitive impairment or mild dementia stages of AD as well as have confirmed presence of Aβ pathology before starting therapy.

Jaypirca (pirtobrutibib)
by Eli Lily

The first non-covalent (reversible) Bruton's tyrosine kinase inhibitor (BTKi) was approved for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTKi. Currently a confirmatory trial is enrolling patients, however the BRUIN trial that included 120 patients, showed an overall response rate of 50% including a complete response rate of 13% and partial response rate of 38%.

Orserdu (elacestrant)
by Stemline Therapeutics

An oral selective estrogen receptor degrader (SERD), called Orserdu was approved on January 27, 2023 for the treatment of postmenopausal women or adult men with estrogen receptor-positive (ER+), HER2-negative (HER2–), ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. Positive outcomes during the EMERALD trial showing a 45% decrease in risk of disease production when compared to current standard of care is what led to the approval.