Kroger Prescription Plans

Q3 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.

Carvykti (Ciltacabtagene autoleucel)
by Janssen/Legend Biotech

Pyrukynd (mitapivat)
by Agios Pharmaceuticals

Ibsrela (tenapanor)
by Ardelyx

Vonjo (pacritinib)
by CTI BioPharma

Opdualag (nivolumab/relatlimab)
by Bristol Myers Squibb

Quviviq (daridorexant)
by Idorsia Pharmaceuticals

Pluvicto (lutetium Lu 177 vipivotide tetraxetan)
by Janssen/Legend Biotech

Camzyos (mavacamten)
by Bristol Myers Squibb

Mounjaro (daridorexant)
by Eli Lilly

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Carvykti (Ciltacabtagene autoleucel)
by Janssen/Legend Biotech

On February 28th, 2022, the US Food and Drug Administration (FDA) approved Carvykti (Ciltacabtagene autoleucel) for treatment of relapse or refractory multiple myeloma. Carvykti is a B Cell maturation antigen (BCMA) directed Chimeric Antigen Receptor T-Cell (CAR-T) immunotherapy. The approval of Carvykti was based on the CARTITUDE-1 trial that found an overall response rate of 97.9% and 78.4% of patients having a stringent complete response. Carvykti like many CAR-T therapy, has a risk evaluation and mitigation strategy (REMS) program that should be considered. Carvykti is the second FDA approved CAR-T treatment for relapse or refractory multiple myeloma after Abecma.

Pyrukynd (mitapivat)
by Agios Pharmaceuticals

On February 17th, 2022, the US Food and Drug Administration (FDA) approved Pyrukynd for treatment of hemolytic anemia in adult with pyruvate kinase deficiency (PKD). Pyrukynd works as a pyruvate kinase activator. Pyrukynd is the first FDA approved treatment for pyruvate kinase deficiency. Before this, the only management of PKD was through supportive action there was no treatment. Approval was based on the ACTIVATE and ACTIVATE-T trials which found that 40% of patients saw an increase in Hemoglobin and 33% of patients received >33% less red blood cell units while being treated with Pyrukynd.

Ibsrela (tenapanor)
by Ardelyx

On September 12th, 2019, the US Food and Drug Administration (FDA) approved Ibsrela for treatment of irritable bowel syndrome with constipation in adults. Despite this, the drug had not been released until 2022. Ibsrela is a Sodium/Hydrogen Exchanger (NHE3) Inhibitor. Initial approval of Ibsrela was based on two Phase 3 studies T3MPO-1 and T3MPO-2. In both studies it was found patients had improvement in abdominal pain and spontaneous bowel movements. While Ibsrela is the first NHE3 for irritable bowel syndrome there are many other options on the market.

Vonjo (pacritinib)
by CTI BioPharma

On February 28th, 2022, the US Food and Drug Administration (FDA) approved Vonjo (pacritinib) for the treatment of adults with intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocytopenia) myelofibrosis (MF) with severe thrombocytopenia (defined as a platelet count below 50×10^9/L). Vonjo is an oral kinase inhibitor that targets multiple tyrosine kinases such as JAK2, IRAK1, and FLT3, without inhibiting JAK1. This novel mechanism of action helps decrease amount of myelosuppression. This is the first FDA-approved medication for patients with MF with severe thrombocytopenia. There is no long-term data available, but the PACIFICA trial is ongoing which will look for long-term effect.

Opdualag (nivolumab/relatlimab)
by Bristol Myers Squibb

On March 18th, 2022, the US Food and Drug Administration (FDA) approved Opdualag (nivolumab/relatlimab) for the treatment of adults and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. Opdualag is the first fixed-dose immune checkpoint inhibitor that combines a programmed death 1 (PD-1) – blocking antibody with a lymphocyte-activation gene 3 (LAG-3) – blocking antibody. In the RELATIVITY-047 Trial Opdualag was compared to Opdivo (nivolumab) alone; the median progression free survival was 10.1 months and 4.6 months, respectively. Prior to Opdualag approval the combination of Opdivo + Yervoy was the initial therapy of choice and has mature 5-year survival data. Opdualag will need to demonstrate mature survival data to determine if it will replace Opdivo + Yervoy as 1st line therapy.

Quviviq (daridorexant)
by Idorsia Pharmaceuticals

On January 7th, 2022, the US Food and Drug Administration (FDA) approved Quiviviq (daridorexant) for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Quviviq joins Belsomra (suvorexant) and Dayvigo (lemborexant) in the dual orexin receptor antagonist (DORA) class, which suppresses the wake drive. There are no head-to-head trials comparing Quviviq to any "Z-drugs" (zolpidem, eszopiclone, zaleplon, etc.).

Pluvicto (lutetium Lu 177 vipivotide tetraxetan)
by Janssen/Legend Biotech

On March 23rd, 2022, the US Food and Drug Administration (FDA) approved Pluvicto (lutetium Lu 177 vipivotide tetraxetan) for the treatment of adult patients with prostate-specific membrane antigen (PMSA) – positive metastatic castration resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy. Pluvicto works by targeting PMSA with a radioactive PMSA-specific ligand. This is the first FDA approved 3rd agent for mCRPC. In the VISION clinical trial, Pluvicto + best standard of care reduced risk of death by 38% compared to best standard of care alone.

Camzyos (mavacamten)
by Bristol Myers Squibb

On April 28th, 2022, the U.S. Food and Drug Administration (FDA) approved Camzyos (mavacamten) for the treatment of adult patients with hypertrophic cardiomyopathy with left ventricular outflow tract obstruction, as long as their left ventricular ejection fraction LVEF is $\geq$ 55%. Camzyos is the first FDA approved myosin inhibitor for obstructive hypertrophic cardiomyopathy. The approval of Camzyos was based on the EXPLORER-HCM trial a phase 3, randomized, parallel, double-blinded trial over 30 weeks. The trial showed that the Camzyos group showed 37% met the primary outcomes than 17% in the placebo group. At the moment, Camzyos is the only treatment approved for obstructive hypertrophic cardiomyopathy and not just symptom management.

Mounjaro (daridorexant)
by Eli Lilly

On May 13th, 2022, the US Food and Drug Administration (FDA) approved Mounjaro (tirzepatide) for the treatment of type 2 diabetes, as an adjunct therapy to diet and exercise. Mounjaro is a novel glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide 1 (GLP-1) receptor agonist. Mounjaro was studied in five phase-3 trials (SURPASS 1, 2, 3, 4, 5). In these trials Mounjaro demonstrated greater A1c lowering, and weight loss compared to Ozempic 1 mg (semaglutide). Even though Mounjaro has a novel mechanism of action, it most likely will still be managed similarly to the GLP-1 receptor agonists. Mounjaro will have a 10% increase in price compared to Eli Lilly's Trulicity (dulaglutide).
