Kroger Prescription Plans

Q4 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.

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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.

Lumakras *(sotorasib)*
by Amgen

Truseltiq *(infigratinib)*
by QED Therapeutics

Bylvay *(odevixibat)*
by Albireo Pharma

Rezurock *(belumosudil)*
by Kadmon Pharmaceuticals

Rylaze *(asparaginase erwinia chrysanthemi)*
by Jazz Pharmaceuticals

Saphnelo *(anifrolumab)*
by AstraZeneca

Nexviazyme *(avalglucosidase alfa)*
by Sanofi Genzyme

For more information regarding these products or if you have any questions regarding our innovative clinical solutions and what KPP is doing to control drug costs, please contact:

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Lumakras (sotorasib)

by Amgen

On May 28, 2021, the U.S. Food and Drug Administration (FDA) approved Lumakras (sotorasib) as the first treatment for adult patients with KRAS G12C–mutated non–small cell lung cancer (NSCLC) who have received at least one prior systemic therapy. In human cancers, KRAS is the most frequently mutated oncogene and accounts for roughly one-quarter of mutations in NSCLC. These mutations are often associated with resistance to targeted therapies and poor outcomes in patients. The approval of Lumakras includes mutations called KRAS G12C, which accounts for about 13% of mutations in NSCLC. Lumakras is dosed as 960mg orally once daily. As part of its accelerated approval, the FDA is requiring a post-marketing trial to investigate whether a lower dose will have a similar clinical effect. Amgen is currently studying Lumakras as a potential treatment for other cancers.

Truseltiq (infigratinib)

by QED Therapeutics

In mid-2021, the U.S. Food and Drug Administration (FDA) approved Truseltiq (infigratinib) for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma (CCA) harboring a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement. Truseltiq is a tyrosine kinase inhibitor (TKI) which works by targeting the FGFR protein, blocking downstream activity. The drug is available as 25-mg and 100-mg capsules in 21-day blister cards. Truseltiq is not currently FDA-approved for any other indication in the United States; however, ongoing clinical studies are evaluating its use for first-line treatment of CCA, urothelial carcinoma, and other solid tumors. We expect that Truseltiq will experience direct competition from Incyte's Pemazyre (pemigatinib), another FGFR inhibitor.

Bylvay (odevixibat)

by Albireo Pharma

In late July 2021, the U.S. Food and Drug Administration (FDA) approved Bylvay (odevixibat) for the treatment of pruritus in patients three months of age and older with progressive familial intrahepatic cholestasis (PFIC). The approval of Bylvay represents the first and only FDA-approved medication to treat PFIC, an ultra-rare group of genetic disorders that disrupt bile formation. This condition usually develops in infancy, although it can develop into young adulthood, and is characterized by cholestasis, jaundice, and intense pruritis. Albireo estimates that there are roughly 600 patients with PFIC living in the United States. The approval of Bylvay was possible due to two clinical trials, PEDFIC 1 and PEDFIC 2, which included 62 and 79 patients, respectively, and demonstrated improved pruritis and reduced serum bile acids. There are no other FDA approved products currently on the market for this condition.

Rezurock (belumosudil)

by Kadmon Pharmaceuticals

On July 16, 2021, the U.S. Food and Drug Administration (FDA) approved Rezurock (belumosudil) for adult and pediatric patients ≥12 years of age with chronic graft-versus-host disease (cGVHD) after the failure of at least two prior lines of systemic therapy. Graft-versus-host disease (GVHD) is common following hematopoietic stem cell transplantation (HSCT). Estimates indicate approximately 10,000 allogeneic transplants are performed in the United States every year, with roughly half of patients developing cGVHD. Rezurock is the first and only FDA-approved rho-associated, coiled-coil kinase 2 (ROCK2) inhibitor. The inhibition of ROCK2 is thought to improve immune balance and reduce fibrosis in affected organs. Rezurock is likely to be available via limited distribution channels in select specialty pharmacies by the end of 2021.

Rylaze (asparaginase erwinia chrysanthemi)

by Jazz Pharmaceuticals

In mid-summer 2021, the U.S. Food and Drug Administration (FDA) approved Rylaze (asparaginase erwinia chrysanthemi) as a component of a chemotherapy regimen to treat acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients one month of age and older who have developed a hypersensitivity to the Escherichia coli-derived asparaginase products used most commonly for treatment. Since the end of the 20th century, asparaginase has been an important, widely-used component of chemotherapy treatment for patients with ALL/LBL, the most common form of cancer in children. Most asparaginase products are derived from the bacteria Escherichia coli (E. coli). Unfortunately, up to a third of these patients develop hypersensitivity reactions to native E. coli asparaginase, thereby limiting its use. Until the approval of Rylaze, Jazz's Erwinaze (asparaginase Erwinia chrysanthemi) was the only other FDA-approved drug for patients who are allergic to asparaginase, but short supply issues have limited its availability over the last several years; Erwinaze is no longer being distributed in the United States. Results from clinical trials shows that the recommended dose of Rylaze provides target levels of asparaginase activity in 94% of patients. Rylaze has been commercially available since July 20, 2021.

Saphnelo (anifrolumab)

by AstraZeneca

On July 30, 2021, the U.S. Food and Drug Administration (FDA) approved Saphnelo (anifrolumab), a first-in-class type I interferon inhibitor, for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy. Systemic lupus erythematosus (SLE) is a chronic autoimmune disorder that leads to inflammatory organ damage throughout the body. Untreated SLE can lead to irreversible damage in vital organs such as the brain and lungs. Saphnelo is a fully human monoclonal antibody that binds to subunit 1 of the type I IFN receptor, blocking the activity of type I IFNs. Up to 80% of adults with SLE have increased type I IFN signaling, which is associated with increased disease severity. Saphnelo's approval represents the first approval for a type I interferon receptor antagonist and the most recent treatment approved for SLE since Benlysta (belimumab) was approved in 2011. In addition to the existing intravenous route, AstraZeneca is currently investigating subcutaneous (SC) delivery of Saphnelo as well as its use in lupus nephritis – two areas which would allow it to compete more closely with Benlysta.

Nexviazyme (avalglucosidase alfa)

by Sanofi Genzyme

On August 6, 2021, the U.S. Food and Drug Administration (FDA) approved Nexviazyme (avalglucosidase alfa) intravenous infusion, indicated for the treatment of patients one year of age and older with late-onset Pompe disease. Pompe disease causes a deficiency of the enzyme acid alpha-glucosidase (GAA), which causes lysosomal glycogen accumulation in skeletal, cardiac, and smooth muscles. Pompe disease typically presents as infantile-onset Pompe disease (IOPD) or late-onset Pompe disease (LOPD), with LOPD being the less severe form. According to Sanofi, there are roughly 3,500 patients in the United States with Pompe disease (including both IOPD and LOPD). Currently, Lumizyme is the only other FDA-approved treatment for Pompe disease on the market, with indications for both IOPD and LOPD. Nexviazyme (avalglucosidase alfa) and Lumizyme (alglucosidase alfa) are structurally and mechanistically similar. Nexviazyme and Lumizyme were studied head-to-head in the Phase 3 clinical trial, COMET. Results from that trial supported the non-inferiority (and subsequent non-superiority) of both products.