Optum Rx®

Pipeline insights summary

Drugs to watch.

Injectible

Respiratory syncytial virus (RSV) vaccines

We review two new vaccines for RSV.

Infants, young children, and older adults are most at risk for severe RSV infection, including serious illness or death. Each year, 58,000 to 80,000 children and 60,000 to 120,000 adults over age 65 are hospitalized from RSV.

RSV vaccine 1: Brand name: Arexvy®. Expected FDA decision: May 3, 2023.

Arexvy, from GSK, is a vaccine to prevent RSV in adults aged 60 years and older. In trials, Arexvy achieved 82.6% efficacy in adults aged 60 years and older.

RSV vaccine 2: Brand name: Abrysvo™. Expected FDA decision: May 2023.

Pfizer's RSV vaccine, Abrysvo, is also under review for adults aged 60 years and older. In trials, Abrysvo achieved 85.7% efficacy against severe RSV.

Pfizer has also submitted trial results for Abrysvo in pregnant patients to help protect newborns and young infants from RSV disease after birth. An FDA decision for this use is expected in August 2023.

Infused

Delandistrogene moxeparvovec: Brand name to be determined. Expected FDA decision: May 29, 2023

Delandistrogene moxeparvovec is a gene therapy from Sarepta Therapeutics. It is for treating ambulatory patients with Duchenne muscular dystrophy (DMD). DMD is a genetic malfunction that causes weakness and wasting of the muscles, primarily in boys.

Trial data suggests this gene therapy is altering the trajectory of DMD. Long-term data is limited, but 2 and 4-year results provide some evidence of sustained stabilizing of function.

The costs for other one-time gene therapies are high. Prices range from $2.1 million (Zolgensma® for spinal muscular atrophy) to $3.5 million (Hemgenix® for hemophilia B).

Oral

Obeticholic acid: Brand name to be determined. Expected FDA decision: June 23, 2023.

Obeticholic acid, from Intercept Pharmaceuticals, is for patients with nonalcoholic steatohepatitis (NASH). NASH is a very common chronic condition in the U.S. with millions of patients potentially eligible for treatment.

Overall trial results for obeticholic acid were modest. Also, use of obeticholic acid is associated with an increase in low-density lipoprotein cholesterol (LDL-C). Still, obeticholic acid would potentially be the first FDA approved treatment for NASH.

Intercept is expected to market obeticholic acid for NASH under its' own brand name with indication-specific pricing. However, obeticholic acid is currently available under the brand name Ocaliva® to treat primary biliary cholangitis (PBC) and costs approximately $105,000 per year.

Optum