TREMFYA® receives FDA approval to treat ulcerative colitis.

Cliff Dominy PhD Sep 16, 2024

Johnson & Johnson (NYSE: JNJ) has announced that their monoclonal antibody TREMFYA® (guselkumab) has received FDA approval to treat active ulcerative colitis[1].

TREMFYA® is a novel, dual-purpose monoclonal antibody capable of binding (in vitro) to both interleukin-23 (IL-23) and the CD64 cells that express it. IL-23 is a pro-inflammatory cytokine implicated in several diseases, including ulcerative colitis. The targeted CD64 cells produce most, but not all, of the IL-23 in the body.

The QUASAR trial evaluated the monoclonal antibody's efficacy against active ulcerative colitis. Phase 3 studies, conducted in a population resistant to conventional treatment, concluded in May 2024.

Christopher Gasink, MD, Vice President of Medical Affairs at Johnson & Johnson, noted: "In the QUASAR clinical program, TREMFYA® demonstrated high reported rates of endoscopic remission at one year of treatment, continuing to raise the bar for efficacy in the treatment of this inflammatory bowel disease."

Early Quasar results (by four weeks) showed statistically significant improvement in reducing early disease symptoms. By forty-four weeks, TREMFYA® had met its primary endpoint of clinical remission, defined as significantly reduced rectal bleeding, stool scores, and endoscopically confirmed intestinal mucosal repair.

TREMFYA® has received prior FDA approval to treat severe plaque psoriasis (2017) and active psoriatic arthritis (2020). A new application was filed in June 2024 to examine the drug's efficacy in treating active Crohn’s disease, the other member of the Inflammatory Bowel Disease family.

The drug's safety has already been well-studied in humans. The most common adverse event reported was an increased risk of respiratory tract infections[2,3]. More severe events include itching, swelling, hives, and low blood pressure, which are consistent with an allergic reaction to the drug.

Johnson & Johnson, through its pharmaceutical division Janssen, has several anti-inflammatory drugs in its stable. These drugs, targeting different components of the inflammatory response, allow the company to conduct combination therapy trials in the future. Combination therapy is showing much promise in putting ulcerative colitis into remission[4].

The Pharma giants' options include Stelara® (for Crohn’s Disease, ulcerative colitis, and plaque psoriasis), Simponi® (for rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis), and Remicade® (for Crohn's disease, ulcerative colitis, and rheumatoid arthritis).

Given Johnson & Johnson's product position in the $104 billion global anti-inflammatory market (2022 numbers), it's no wonder that financial analysts are currently bullish on stock [5].

References

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