FDA Approves Updated Indication for Upadacitinib in Patients With IBD

Key Takeaways

- Upadacitinib is a JAK inhibitor approved for several immune-mediated inflammatory diseases, including ulcerative colitis and Crohn's disease.
- The updated FDA indication allows upadacitinib use before TNF blockers in certain patients with ulcerative colitis and Crohn's disease.
- Phase 3 trials demonstrated upadacitinib's efficacy in achieving clinical remission and endoscopic response in inflammatory bowel disease.
- The label update offers healthcare providers more treatment options for patients with moderately to severely active IBD when TNF blockers are inadvisable.

The approved indication now includes adults with moderately to severely active ulcerative colitis and Crohn disease who have not been treated with tumor necrosis factor blocking agents.

The FDA approved a supplemental new drug application that updates the indication statement of upadacitinib (Rinvoq; AbbVie) for the treatment of adults with moderately to severely active ulcerative colitis and Crohn disease. This updated indication now allows the use of upadacitinib prior to the use of tumor necrosis factor (TNF) blocking agents in patients for whom use of these treatments is clinically inadvisable and who have received at least 1 approved systemic therapy.1

What is Upadacitinib?

Upadacitinib is a Janus kinase (JAK) inhibitor that is approved for treatment in several immune-mediated inflammatory diseases, including rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis and Crohn disease, the most common forms of inflammatory bowel disease (IBD). In human leukocyte cellular assays, upadacitinib inhibited cytokine-induced STAT phosphorylation mediated by JAK1 and JAK1/JAK3 more effectively than JAK2/JAK2-mediated STAT phosphorylation.1 Upadactinib was initially approved for colitis in March 20222, and for Crohn disease in May 2023.3 Both approvals were initially for moderately to severely active disease in patients who demonstrated an inadequate response or intolerance to 1 or more TNF blockers.1-3

IBD is characterized by chronic inflammation to the gastrointestinal tract because the immune system targets the mucosa, or lining, of the gut. Crohn disease manifests as inflammation most commonly between the small intestine and the colon, whereas ulcerative colitis impacts the large intestines. Both diseases are progressive, meaning they worsen over time and may lead to life-threatening complications or surgery. The signs and symptoms of IBD are unpredictable, causing a physical and emotional burden on patients with the disease.1-3

Clinical Trials for Upadacitinib

The initial approval in ulcerative colitis was based on results from the randomized, double-blind, placebo-controlled, phase 3 trials U-ACHIEVE (NCT02819635)4 and U-ACCOMPLISH (NCT02819635)5, which demonstrated 45 mg of upadacitinib once per day for an 8-week period resulted in clinical remission in approximately 26% and 33% of patients compared with placebo (5% and 4%). During the maintenance trial, 42% and 52% of patients who received 15 mg and 30 mg of upadacitinib, respectively, achieved clinical remission at week 52 compared with 12% of patients in the placebo group. Patients also achieved corticosteroid-free remission.2,4,5

The initial approval for Crohn disease was based on findings from a trio of phase 3 clinical trials, including the 2 induction studies, U-EXCEED (NCT03345836)6 and U-EXCEL (NCT03345849)7, and 1 maintenance study, U-ENDURE (NCT03345823)8. These trials evaluated the efficacy and safety of 45 mg of upadacitinib once per day as an induction therapy and 15 and 35 mg of upadacitinib once per day as maintenance therapy in adults with moderately to severely active Crohn disease. Across all 3 studies, investigators found that significantly more participants treated with upadacitinib achieved the coprimary end points of clinical remission and endoscopic response. Additionally, investigators observed clinical remission measured by the Crohn’s Disease Activity Index by patient-reported symptoms of stool frequency/abdominal pain.3,6-8

"At AbbVie, we are committed to addressing the ongoing needs of patients living with inflammatory bowel disease," Kori Wallace, MD, PhD, vice president, global head of immunology clinical development at AbbVie, said in a news release. "Ulcerative colitis and Crohn disease can impact every aspect of a patient's life. This label update gives healthcare providers the option to prescribe [upadacitinib] for patients with moderately to severely active IBD after the use of 1 approved systemic therapy if TNF blockers are deemed clinically inadvisable by the prescribing physician."1

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