Pfizer Logo

Pfizer Announces FDA and EMA Acceptance of Etrasimod Regulatory Submissions for Ulcerative Colitis

Wednesday, December 21, 2022 - 06:45am

- Filings based on two Phase 3 trials demonstrating significant clinical remission versus placebo and safety profile consistent with previous studies

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review a New Drug Application (NDA) for etrasimod for individuals living with moderately-to-severely active ulcerative colitis (UC). The FDA's decision is expected in the second half of 2023. The European Medicines Agency (EMA) has also accepted the Marketing Authorization Application (MAA) for etrasimod in the same patient population with the decision anticipated in the first half of 2024.

Etrasimod is an oral, once daily, selective sphingosine-1-phosphate (S1P) receptor modulator designed for optimized pharmacology and engagement of S1P receptors 1, 4, and 5. In addition to UC, it is being investigated for a range of other immuno-inflammatory diseases.

UC is a chronic and often debilitating condition[1] that affects an estimated 3.8 million people in North America and Europe.[2] Symptoms of UC can include chronic diarrhea with blood and mucus, abdominal pain, and urgency.[3,4] UC can have a significant effect on work, family, and social activities. There is a need for additional advanced therapeutic options in UC that are oral, effective, and have a favorable risk-benefit profile.

"Ulcerative colitis can substantially impact the day-to-day lives of people living with this chronic and often debilitating disease, and many patients never achieve nor maintain remission on today's therapies," said Michael Corbo, PhD, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. "We believe that etrasimod, if approved, has the potential to be a best-in-class, first-line advanced therapy for people living with moderately-to-severely active ulcerative colitis, based on its clinical profile."

These submissions were based on previously announced results from the ELEVATE UC Phase 3 registrational program (ELEVATE UC 52 and ELEVATE UC 12) that evaluated the safety and efficacy of etrasimod 2 mg once daily on clinical remission in UC patients who had previously failed or were intolerant to at least one conventional, biologic, or Janus kinase (JAK) inhibitor therapy. Both randomized, double-blind, placebo-controlled studies achieved all primary and key secondary endpoints, with a safety profile consistent with previous studies.

About ELEVATE UC 52 and ELEVATE UC 12
ELEVATE UC 52 and ELEVATE UC 12 are pivotal trials that are part of the ELEVATE UC Phase 3 registrational program.[5]

ELEVATE UC 52 is a randomized, double-blind, placebo-controlled trial that utilized a treat-through design comprising of a 12-week induction period followed by a 40-week maintenance period. Beginning at week 12, all patients could continue their randomized treatment; patients whose disease had not improved or had worsened compared to baseline could discontinue and, if eligible, enroll in an open-label extension study. The primary objective of this trial was to assess the safety and efficacy of etrasimod 2 mg once daily on clinical remission after both 12 and 52 weeks. The primary endpoint is based on the 3-domain, modified Mayo score (MMS). In ELEVATE UC 52, clinical remission was 27.0% for patients receiving etrasimod compared to 7.4% for patients receiving placebo at week 12 (19.8% differential, P?.001) and was 32.1% compared to 6.7% at week 52 (25.4% differential, P?.001). Statistically significant improvements were attained in all key secondary endpoints, including endoscopic improvement, symptomatic remission, and mucosal healing at weeks 12 and 52, and corticosteroid-free remission and sustained clinical remission at week 52.

ELEVATE UC 12 is a randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of etrasimod 2 mg once-daily in subjects with moderately-to-severely active UC. The primary objective of this trial was to assess the safety and efficacy of etrasimod on clinical remission at 12 weeks assessed by the FDA-required, 3-domain, MMS. In ELEVATE UC 12, clinical remission was achieved among 24.8% of patients receiving etrasimod compared to 15.2% of patients receiving placebo (9.7% differential, P=.0264). All key secondary endpoints were met at week 12, including endoscopic improvement, symptomatic remission, and mucosal healing.

In ELEVATE UC 12, a similar proportion of patients experienced treatment-emergent adverse events (AEs) between etrasimod 2 mg and placebo treatment groups, while in ELEVATE UC 52, it was higher in the etrasimod 2 mg group compared to placebo. The proportion of patients experiencing serious AEs was similar between treatment groups in both trials. The most common treatment-emergent AEs in 3% or more of etrasimod-treated patients and greater than placebo up to week 52 in either trial were headache, worsening of UC, COVID-19 infection, dizziness, pyrexia, arthralgia, abdominal pain and nausea. There were no reports of bradycardia or atrioventricular block as serious AEs. Data support initiation of etrasimod treatment does not require complex up-titration regimen.

Nearly two-thirds of patients in ELEVATE UC 52 and ELEVATE UC 12, respectively, were naïve to biologic or JAK inhibitor therapy.

Pfizer Inc.: Breakthroughs that Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety, and value in the discovery, development, and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments, and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments, and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice
The information contained in this release is as of December 21, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about etrasimod, including its potential benefits, best in class potential and an NDA filed with the FDA and an MAA filed with the EMA for etrasimod for individuals living with moderately-to-severely active ulcerative colitis , that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in particular jurisdictions for etrasimod; whether and when the applications filed with the FDA and EMA and any such other applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether etrasimod will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of etrasimod; the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

[1] Crohn's and Colitis Foundation. What is Ulcerative Colitis? Available at: https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis. Accessed December 16, 2022.
[2] Seyedian, SS. A review of the diagnosis, prevention, and treatment methods of inflammatory bowel disease. *J Med Life.* 2019;12(2):113-122.
[3] Hanauer SB. Inflammatory bowel disease. *N Engl J Med.* 1996;334(13):841-8.
[4] Irvine EJ. Quality of Life of Patients with Ulcerative Colitis: Past, Present, and Future. Inflammatory Bowel Diseases. 2008;14(4):554-563.
[5] Sandborn WJ, et al. Etrasimod 2mg once daily as treatment for moderately to severely active ulcerative colitis: results from the phase 3 ELEVATE UC 52 and ELEVATE UC 12 trials, presented at DDW 2022; Abstract 968a.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230104005006/en/

Media Contact: +1 (212) 733-1226
PfizerMediaRelations@Pfizer.com

Investor Contact: +1 (212) 733-4848
IR@Pfizer.com

Source: Pfizer Inc.