Pfizer Logo

Pfizer Presents ELEVATE Pivotal Findings Demonstrating Etrasimod's Potentially Best-in-Class Profile in Ulcerative Colitis

Tuesday, May 24, 2022 - 06:45am

- Analyst call will be held to discuss data today at 4:00 PM Eastern Time

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced detailed results from two pivotal studies that make up the ELEVATE UC Phase 3 registrational program evaluating etrasimod, a once-daily, oral, selective sphingosine 1-phosphate (S1P) receptor modulator for the treatment of moderately-to-severely active ulcerative colitis (UC). These data were presented as a late-breaker presentation (abstract number 968a) at Digestive Disease Week (DDW) 2022.

Both Phase 3, multi-center, randomized, placebo-controlled trials achieved all primary and key secondary endpoints, with etrasimod demonstrating a safety profile consistent with previous studies. In the 52-week ELEVATE UC 52 study, 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). In the 12-week ELEVATE UC 12 study, clinical remission was achieved among 24.8% of patients receiving etrasimod compared to 15.2% of patients receiving placebo (9.7% differential, *P*=.0264).

UC is a chronic and often debilitating inflammatory bowel disease[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.[4]

"Etrasimod could offer a differentiated clinical profile for people living with moderately-to-severely active ulcerative colitis considering the clear benefit it has shown over 52 weeks in a treat-through trial design, its mechanism of action, and its unique pharmacologic properties," said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. "Patients often need multiple options to help manage their disease and there is a significant need for new therapies. In the ELEVATE clinical program, etrasimod has shown an encouraging balance of efficacy and safety that we believe could have a meaningful impact for patients and physicians, if approved."

The 52-week ELEVATE UC 52 trial utilized a treat-through design which closely mimics real-world clinical practice. Statistically significant improvements were attained in all key secondary endpoints in ELEVATE UC 52. These included endoscopic improvement, symptomatic remission, and mucosal healing at weeks 12 and 52, and corticosteroid-free remission and sustained clinical remission at week 52. All key secondary endpoints were also met at week 12 in ELEVATE UC 12. These included endoscopic improvement, symptomatic remission, and mucosal healing.

Treatment-emergent adverse events (AEs), including serious AEs, were 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.

The data from ELEVATE UC 52 & UC 12 are expected to form the basis for planned future regulatory filings, which will be initiated later this year. Additional information about the studies can be found at www.clinicaltrials.gov under the identifiers NCT03945188, NCT03996369, and NCT03950232.

Etrasimod was developed by Arena Pharmaceuticals, which was recently acquired by Pfizer.

Pfizer Conference Call

Pfizer Inc. invites Pfizer investors and the general public to view and listen to a webcast of a live conference call with investment analysts at 4 p.m. ET on May 24.

To view and listen to the webcast visit Pfizer's website at www.pfizer.com/investors or directly at https://pfizer.rev.vbrick.com/#/events/333186b6-252b-4c60-be45-947638abd93f. Information on accessing and pre-registering for the webcast will be available at www.pfizer.com/investors beginning today. Participants are advised to pre-register in advance of the conference call.

You can listen to the conference call by dialing either (833) 708-1779 in the United States or Canada or (602) 585-9859 outside of the United States and Canada. The password is "9991403." Please join the call five minutes prior to the start time to avoid operator hold times.

The transcript and webcast replay of the call will be made available on Pfizer's website at www.pfizer.com/investors within 24 hours after the end of the live conference call and will be accessible for at least 90 days.

About Etrasimod

Etrasimod is an oral, once-a-day, selective sphingosine 1-phosphate (S1P) receptor modulator designed for optimized pharmacology and engagement of S1P receptors 1, 4, and 5. It is being investigated for a range of immuno-inflammatory diseases, including ulcerative colitis, Crohn's disease, atopic dermatitis, eosinophilic esophagitis, and alopecia areata.

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.

ELEVATE UC 52 is a randomized, double-blind, placebo-controlled trial that utilized a treat-through design. 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. All patients that dropped out of the study across either treatment arm over the 52-week study was counted as a non-responder. The primary endpoint is based on the 3-domain, modified Mayo score (MMS). Key secondary measures included 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, modified Mayo score. Key secondary measures included endoscopic improvement, symptomatic remission, and mucosal healing.

62.6% of etrasimod-treated patients in both trials and 61.8% and 62.9% of placebo-treated patients in ELEVATE UC 52 and ELEVATE UC 12, respectively, were naïve to biologic or JAK inhibitor therapy.

About Digestive Disease Week

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and virtual meeting from May 21-24, 2022. The meeting showcases more than 3,100 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

About Pfizer Inflammation & Immunology

At Pfizer Inflammation & Immunology, we strive to deliver breakthroughs that enable freedom from day-to-day suffering for people living with autoimmune and chronic inflammatory diseases, which can be debilitating, disfiguring and distressing, dramatically affecting what they can do. With a focus on immuno-inflammatory conditions in Rheumatology, Gastroenterology and Medical Dermatology, our current portfolio of approved medicines and investigational molecules spans multiple action and delivery mechanisms, from topicals to small molecules, biologics and biosimilars. The root cause of many immunological diseases is immuno-inflammation, which requires specifically designed agents. Our differentiated R&D approach resulted in one of the broadest pipelines in the industry, where we purposefully match molecules to diseases where we believe they can make the biggest difference. Building on our decades-long commitment and pioneering science, we continue to advance the standard of care for patients living with immuno-inflammatory diseases and are working hand-in-hand with patients, caregivers and the broader healthcare community on healthcare solutions for the many challenges of managing chronic inflammatory diseases, allowing patients to live their best lives.

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 May 24, 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 and planned regulatory filings, 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 any jurisdictions for etrasimod; whether and when any such 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 .

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[1] Crohn's and Colitis Foundation. What is Ulcerative Colitis. Available at: What is Ulcerative Colitis? | Crohn's & Colitis Foundation (crohnscolitisfoundation.org). Accessed April 26, 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. Available at: A review of the diagnosis, prevention, and treatment methods of inflammatory bowel disease - PMC (nih.gov). Accessed April 26, 2022.
[3] Hanauer SB. Inflammatory bowel disease. *N Engl J Med.* 1996;334(13):841-8. Available at: Inflammatory Bowel Disease | NEJM. Accessed April 26, 2022.
[4] Irvine EJ. Quality of Life of Patients with Ulcerative Colitis: Past, Present, and Future. Inflammatory Bowel Diseases. 2008;14(4):554-563. Available at: Quality of life of patients with ulcerative colitis: Past, present, and future | Inflammatory Bowel Diseases | Oxford Academic (openathens.net). Accessed April 26, 2022.

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