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Pfizer Announces Positive Top-line Results from Yearlong Phase 3 Trial of Etrasimod in Ulcerative Colitis, Underscoring Best-in-Class Potential

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ELEVATE UC 52 met the co-primary endpoints of clinical remission at both weeks 12 and 52 and all key secondary endpoints

- Etrasimod demonstrated a safety profile consistent with previous studies

NEW YORK--(BUSINESS WIRE)--

Pfizer Inc. (NYSE: PFE) today announced positive top-line results from a second Phase 3 study of etrasimod, an investigational, oral, once-a-day, selective sphingosine 1-phosphate (S1P) receptor modulator in development for the treatment of moderately to severely active ulcerative colitis (UC). The positive 12- and 52-week results from ELEVATE UC 52 follow the recent announcement of positive 12-week findings from the ELEVATE UC 12 trial on March 23.

In this 52-week study, also known as ELEVATE UC 52, etrasimod patients achieved statistically significant improvements in the co-primary endpoints of clinical remission at weeks 12 and 52 when compared to placebo. Statistically significant improvements were attained in all key secondary endpoints at both 12 and 52 weeks. Etrasimod demonstrated a safety profile consistent with previous studies, including the Phase 2 OASIS trial.

The global Phase 3 multi-center, randomized, double-blind, placebo-controlled study enrolled 433 UC patients who had previously failed or were intolerant to at least one conventional, biologic, or Janus kinase (JAK) inhibitor therapy. Participants received etrasimod 2 mg or placebo once-daily. ELEVATE UC 52 utilized a treat-through design in which patients were eligible to continue with their randomized treatment independent of whether they reached the objective criteria of clinical response at week 12.

“For patients suffering with moderate to severe ulcerative colitis, these most recent data further demonstrate the substantial potential benefits of this medicine and clearly confirm its ability to achieve significant induction of remission at 12 weeks and now clinical remission at week 52. These data underscore etrasimod’s potential, if approved, as a best-in-class therapy,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “Etrasimod can potentially provide a new, once-daily, oral option with a rapid onset of action and without first dose titration. Further, we believe the treat-through design of the ELEVATE UC 52 study more accurately reflects a real-world treatment approach than the re-randomization design often used in UC clinical trials.”

Full results from the studies will be submitted for future scientific publication and presentation. These data, along with results from ELEVATE UC 12 and the long-term extension from these two trials (ELEVATE UC OLE), are expected to form the basis for planned future regulatory filings. Pfizer expects to initiate regulatory filings 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.

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.

In a Phase 2, randomized, placebo-controlled, dose-ranging study (OASIS) in moderate to severe UC patients, most patients who achieved clinical response, clinical remission, or endoscopic improvement at week 12 experienced sustained or improved effects up to week 46, with etrasimod 2 mg in the open-label extension. Etrasimod also demonstrated a favorable benefit/risk profile, consistent with safety findings reported in the double-blind portion of OASIS.

About ELEVATE UC 52

ELEVATE UC 52 is one of two pivotal trials that are part of the ELEVATE UC global Phase 3 registrational program. ELEVATE UC 52 is a 2:1 randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of etrasimod 2 mg once-daily in participants with moderately-to-severely active UC. This is a one-year trial evaluating clinical remission at 12 weeks, or induction, and at 52 weeks. ELEVATE UC 52 utilized a treat-through design in which patients were eligible to continue with etrasimod independent of whether they reached clinical response at week 12.

The primary objective of this trial is to assess the safety and efficacy of etrasimod on clinical remission after both 12 and 52 weeks. The primary endpoint is based on the 3-domain, modified Mayo score. Key secondary measures include the efficacy of etrasimod, symptomatic remission, endoscopic improvement, corticosteroid-free remission, and mucosal healing in these participants at time points up to 52 weeks of treatment.

About Ulcerative Colitis

UC is a chronic and often debilitating inflammatory bowel disease[1] that affects many people worldwide, including 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 cramping, and weight loss.[3,4] UC can have a significant effect on work, family and social activities.[4]

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 March 29, 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 March 18, 2022.
[2] Seyedian, SS. A review of the diagnosis, prevention, and treatment methods of inflammatory bowel disease. J Med Life 2019 Apr-Jun; 12 (2): 113-122. Available at: A review of the diagnosis, prevention, and treatment methods of inflammatory bowel disease - PMC (nih.gov). Accessed March 22, 2022.
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[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 March 18, 2022.

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

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

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