Lilly's Mirikizumab Helps Patients Achieve Clinical Remission and Improves Symptoms in Adults with Ulcerative Colitis in 12-Week Phase 3 Induction Study

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- Patients treated with mirikizumab met the primary endpoint of clinical remission and all key secondary endpoints compared to placebo

- LUCENT-1 is the first and only Phase 3 study of an anti-IL-23p19 monoclonal antibody to demonstrate reduced bowel urgency in moderate to severe ulcerative colitis

- Safety results in this study were consistent with that of the previous mirikizumab study in ulcerative colitis and studies with the anti-IL-23p19 antibody class

INDIANAPOLIS, March 16, 2021 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that mirikizumab met the primary and all key secondary endpoints in LUCENT-1, a 12-week Phase 3 induction study evaluating the efficacy and safety of mirikizumab for the treatment of patients with moderate to severe ulcerative colitis (UC). LUCENT-2, a multicenter, randomized, double-blind, placebo-controlled maintenance study of mirikizumab in patients who have completed the 12-week LUCENT-1 induction study is ongoing.

UC is a chronic inflammatory disease of the large intestine, also referred to as the colon, that affects the lining of the colon and may cause small sores, or ulcers, to form.[i] This inflammation can cause abdominal pain, frequent and urgent trips to the bathroom, bloody stools and incontinence.[1] UC can cause significant and debilitating disruptions in daily life. Millions of people live with UC globally.[2]

"There is a continued need for additional treatments that can provide people living with ulcerative colitis relief from their most challenging symptoms," said William J. Sandborn, MD, Professor of Medicine, and Chief, Division of Gastroenterology, University of California San Diego. "Results of this study provide further clinical evidence of the potential for mirikizumab to become the first anti-IL-23p19 biologic for the treatment of ulcerative colitis."

In LUCENT-1, mirikizumab met the primary endpoint of clinical remission at Week 12 compared to placebo ($p<0.0001$). Clinical remission is met when inflammation of the colon is controlled or resolved, leading to normalization or near-normalization of symptoms such as stool frequency and bleeding.

Mirikizumab also achieved all key secondary endpoints compared to placebo at Week 12 in patients with UC with highly statistically significant p-values, including reduced bowel urgency, clinical response, endoscopic remission, symptomatic remission and improvement in endoscopic histologic inflammation. In addition, mirikizumab demonstrated rapid improvement in patient symptoms as early as four weeks after initiating treatment. Mirikizumab also reduced symptoms among patients who had previously not responded to or stopped responding to biologic and/or Janus kinase (JAK) inhibitor therapies.

In the 12-week placebo-controlled induction study of LUCENT-1, the incidence of treatment-emergent adverse events (AEs) and serious AEs among patients treated with mirikizumab was consistent with that of the previous Phase 2 mirikizumab study in UC and studies with the anti-IL-23p19 antibody class. The most common AEs included nasopharyngitis, anemia and headache for both placebo and mirikizumab-treated patients.

"People living with UC often struggle to effectively manage recurring flare ups of the disease," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "With these positive results, we look forward to the continuation of the maintenance study through 52 weeks in hopes of providing a new option to people living with UC."

The full LUCENT study results, including data from LUCENT-2 and LUCENT-3, will be disclosed at a future congress or publication.

"Ulcerative colitis can be debilitating and unpredictable for the hundreds of thousands of people living with this chronic disease," said Dr. Caren Heller, Chief Scientific Officer for the Crohn's & Colitis Foundation. "We're encouraged by these promising results for a potential new treatment that may help provide symptom relief and remission."

About Mirikizumab

Mirikizumab is a humanized IgG4 monoclonal antibody that binds to the p19 subunit of interleukin 23. Mirikizumab is being studied for the treatment of immune diseases, including psoriasis, ulcerative colitis and Crohn's disease.

About the LUCENT Clinical Trial Program

The LUCENT Phase 3 clinical development program for mirikizumab includes LUCENT-1, LUCENT-2 and LUCENT-3. LUCENT-1 (NCT03518086) is a multicenter, randomized, double-blind, placebo-controlled, Phase 3 induction study of mirikizumab in patients with moderate to severe UC who had failed conventional and/or biologic treatments. LUCENT-2 (NCT03524092) is a multicenter, randomized, double-blind, placebo-controlled maintenance study of mirikizumab in patients who have completed the 12-week LUCENT-1 induction study. LUCENT-3 (NCT03519945) is an open label extension study for eligible patients who have participated in mirikizumab UC trials.

The program began in 2018, with full results from the induction and maintenance studies anticipated in early 2022.

About Ulcerative Colitis

Ulcerative colitis is a chronic inflammatory bowel disease that affects the colon.[1] UC occurs when the immune system sends white blood cells into the lining of the intestines, where they produce chronic inflammation and ulcerations.[3] There is an unmet need for additional treatment options for UC that provide meaningful symptom relief, including bowel urgency, and deliver sustained clinical remission.

About Eli Lilly and Company
Lilly is a global health care leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at lilly.com and lilly.com/newsroom. P-LLY

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about mirikizumab as a potential treatment for patients with ulcerative colitis and other diseases and reflects Lilly's current beliefs and expectations. As with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there can be no guarantee that future study results will be consistent with study results to date, that mirikizumab will prove to be a safe and effective treatment or that mirikizumab will receive regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

[1] Overview of Ulcerative Colitis. Crohn's and Colitis Foundation Website. https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis/overview. Accessed February 2021.

[2] Adelphi Data 2017.

[3] What is Ulcerative Colitis? Crohn's and Colitis Foundation Website. http://www.crohnscolitisfoundation.org/what-are-crohns-and-colitis/what-is-ulcerative-colitis/. Accessed February 2021.

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