# Mirikizumab Demonstrates Superiority over Placebo in Phase 3 Maintenance Study in Ulcerative Colitis, Supporting Regulatory Submissions in 2022

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**Significantly more patients treated with mirikizumab maintenance dosing achieved the primary endpoint of clinical remission at one year (52 weeks), and all key secondary endpoints were met**

**Mirikizumab is the first and only anti-IL23p19 to demonstrate maintenance of clinical remission in a Phase 3 study in UC**

INDIANAPOLIS, Dec. 14, 2021 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that mirikizumab met the primary endpoint of clinical remission and all key secondary endpoints at one year in LUCENT-2, a Phase 3 maintenance study evaluating the efficacy and safety of mirikizumab for the treatment of patients with moderately-to-severely active ulcerative colitis (UC). Patients in this study were previously enrolled in a 12-week induction study, LUCENT-1. These results build on the positive outcomes from LUCENT-1.

In LUCENT-2, for patients who achieved clinical response with mirikizumab in the 12-week induction study and were re-randomized to mirikizumab maintenance dosing, a statistically higher proportion met the primary endpoint of clinical remission at one year compared to patients who were re-randomized to placebo ($p<0.001$). Clinical remission is reached when inflammation of the colon is controlled or resolved, leading to normalization or near-normalization of symptoms such as frequent and bloody stools. All key secondary endpoints were also met ($p<0.001$), including significantly higher proportions of patients treated with mirikizumab achieving endoscopic remission, corticosteroid-free remission, resolution or near-resolution of bowel urgency, improvement in endoscopic histologic intestinal inflammation and maintenance of remission, and greater reduction from baseline in bowel urgency symptoms at one year compared to placebo.

"In this maintenance study, treatment with mirikizumab demonstrated clinically meaningful and statistically significant improvements in clinical, endoscopic and histologic measures, including reduction of bowel urgency – a novel endpoint in the LUCENT program," said Bruce E. Sands, M.D., M.S., Dr. Burrill B. Crohn Professor of Medicine, Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at the Icahn School of Medicine at Mount Sinai. "Bowel urgency is one of the most bothersome and disruptive symptoms people living with ulcerative colitis experience, and the LUCENT program leveraged an innovative and systematic patient-centric approach to assess patients' symptoms."

In the placebo-controlled maintenance cohort, the frequency of serious adverse events among patients treated with mirikizumab was numerically lower compared to placebo, and the overall safety profile was consistent with that of the previous mirikizumab studies in UC and other studies within the anti-IL-23p19 antibody class. The most common treatment emergent adverse events reported among patients treated with mirikizumab were nasopharyngitis, arthralgia and exacerbation of ulcerative colitis. Additional adverse events of interest reported among patients treated with mirikizumab included hypersensitivity, injection site reaction, depression, liver enzyme elevation, herpes zoster and oral candidiasis.

"Existing therapies aren't fully meeting the needs of people with ulcerative colitis who still have unresolved symptoms that impact their health and quality of life," said Lotus Mallbris, M.D., Ph.D., vice president of global immunology development and U.S. and global medical affairs at Lilly. "These positive long-term results provide evidence that mirikizumab has the potential to be an effective treatment option and become the first medicine of its kind for people with ulcerative colitis, including those who suffer from bowel urgency."

With these data, Lilly plans to submit a Biologics License Application (BLA) to the FDA for mirikizumab in UC, followed by submissions to other regulatory agencies around the world in the first half of 2022.

"The results announced today are encouraging for those who live with ulcerative colitis," said Michael Osso, President and CEO for Crohn's & Colitis Foundation. "We're excited about potential new options in the inflammatory bowel disease treatment space that may be able to help people living with ulcerative colitis successfully control their disease symptoms and achieve remission."

Topline results from the Phase 3 induction study, LUCENT-1, were announced in March 2021. Data from the Phase 3 LUCENT program, including results from LUCENT-1 and LUCENT-2, will be disclosed at upcoming congresses and in publications in 2022. Additional Phase 3 clinical trials are ongoing for mirikizumab in Crohn's disease.

**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-mediated diseases, including 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 induction study of mirikizumab in patients with moderately-to-severely active ulcerative colitis who have previously failed conventional and/or biologic therapies and/or JAK inhibitors. LUCENT-2 (NCT03524092) is a multicenter, randomized, double-blind, placebo-controlled, Phase 3 maintenance study in patients who completed LUCENT-1. 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.[2] There is an unmet need for additional treatment options for UC that provide meaningful symptom relief, including bowel urgency, and deliver sustained clinical remission. UC can cause significant and debilitating disruptions in daily life. Millions of people live with UC globally.[3]

**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 planned or ongoing studies will be completed as planned, 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 December 2021.
[2] What is Ulcerative Colitis? Crohn's and Colitis Foundation Website. http://www.crohnscolitisfoundation.org/what-are-crohns-and-colitis/what-is-ulcerative-colitis/. Accessed December 2021.
[3] Adelphi Data 2017.

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