DDW 2018: Patients with Moderate-to-Severe Ulcerative Colitis Achieved Clinical and Endoscopic Remission with Mirikizumab in Phase 2 Trial

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- New data are the first safety and efficacy data for an IL-23p19 monoclonal antibody for the treatment of moderate-to-severe ulcerative colitis -

- Lilly will initiate a Phase 3 trial in moderate-to-severe ulcerative colitis this year -

INDIANAPOLIS, June 5, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today new safety and efficacy data from a Phase 2 study evaluating mirikizumab in patients with moderate-to-severe ulcerative colitis (UC). The results showed that patients treated with mirikizumab achieved significantly greater rates of clinical remission at 12 weeks compared to placebo. Detailed results from the Phase 2 trial will be presented today in a late-breaking abstract session at Digestive Disease Week (DDW) in Washington, D.C.

"We are proud to present these Phase 2 results for mirikizumab at DDW, which represent the first public disclosure of data on the safety and efficacy of an IL-23p19 monoclonal antibody in patients with moderate-to-severe UC," said Lotus Mallbris, M.D., vice president, immunology platform team leader, Lilly Bio-Medicines. "These positive data affirm our confidence in the potential for mirikizumab to be an option for people living with immune-mediated diseases looking for a treatment that addresses their life-altering symptoms. We look forward to advancing our Phase 3 clinical development program for mirikizumab in UC, in addition to continuing our ongoing Phase 3 trial for mirikizumab in moderate-to-severe plaque psoriasis."

The Phase 2 study evaluated the safety and efficacy of mirikizumab compared to placebo in patients with moderate-to-severe UC who had previously failed conventional or biologic therapy. In the study, patients were randomized to receive either mirikizumab (50 mg or 200 mg with the possibility of exposure-based increases up to 600 mg, or 600 mg fixed dose) or placebo. The primary and secondary endpoints at 12 weeks were the percentages of patients treated with mirikizumab achieving clinical remission, clinical response, endoscopic healing, endoscopic remission and symptomatic remission.

At 12 weeks, patients achieved the following response rates:

- **Clinical remission**: Across all doses studied, between 11.5 percent to 22.6 percent of patients treated with mirikizumab achieved clinical remission, compared to 4.8 percent of those treated with placebo (nominal p-value < 0.05 for 200 mg dose-adjusted group compared with placebo; other treatment group comparisons yielded non-significant p-values)
- **Clinical response**: Across all doses studied, between 41.3 percent to 59.7 percent of patients treated with mirikizumab achieved clinical response, compared to 20.6 percent of those treated with placebo (nominal p-value < 0.05 for all mirikizumab groups compared with placebo)
- **Endoscopic healing**: Across all doses studied, between 13.1 percent to 30.6 percent of patients treated with mirikizumab achieved endoscopic healing, compared to 6.3 percent of those treated with placebo (nominal p-value < 0.05 for 50 mg and 200 mg dose-adjusted groups compared with placebo; other treatment group comparison yielded non-significant p-value)

Additionally, greater proportions of patients treated with mirikizumab achieved endoscopic remission and symptomatic remission compared to placebo at 12 weeks. The proportion of patients achieving endoscopic remission was not statistically significant.

The incidence of serious adverse events and treatment-emergent adverse events (TEAEs) was similar across treatment groups. Among the most common TEAEs reported across all treatment groups, rates of nasopharyngitis, anemia and headache were similar between mirikizumab and placebo groups; a greater proportion of patients reported worsening of ulcerative colitis in the placebo group compared to patients in the mirikizumab groups.

"I am particularly encouraged by the symptomatic response and remission data we've seen thus far, and look forward to having data from later periods in the study to provide insight about the degree to which endoscopy results continue to improve over time, as we've observed in other clinical programs for UC," said William J. Sandborn, M.D., Chief, Division of Gastroenterology, Professor of Medicine at the University of California San Diego School of Medicine. "Data from this Phase 2 trial indicate that if approved, mirikizumab may be an effective treatment option for patients with moderate-to-severe UC."

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 Ulcerative Colitis

Ulcerative colitis (UC) 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.[1] UC affects millions of patients globally.[2] Early and sustained symptom relief, improvement in the appearance of the mucosa, and clinical remission are important treatment goals for healthcare providers

and patients.[2] There is an unmet need for treatment options for UC that provide meaningful symptom relief and deliver sustained clinical remission.

About the Mirikizumab Phase 2 Trial in UC
The Phase 2, multi-center, randomized, double-blind, placebo-controlled trial was designed to evaluate the safety and efficacy of mirikizumab in patients with moderate-to-severe UC. The primary endpoint in the study was the percentage of patients achieving clinical remission at 12 weeks, as defined by a Mayo rectal bleeding subscore of 0; a stool frequency subscore of 0 or 1, plus a decrease ≥1 from baseline; and an endoscopy subscore of 0 or 1. The study also evaluated secondary endpoints, including clinical response, as defined by a Mayo subscore decrease of ≥2 points and a ≥35 percent change in from induction baseline, excluding PGA; endoscopic healing, as defined by a Mayo endoscopy subscore of 0 or 1; endoscopic remission, as defined by a Mayo endoscopy subscore of 0; and symptomatic remission, as defined by a stool frequency subscore of 0 or 1 and a rectal bleeding subscore of 0. For additional information on this trial, please visit clinicaltrials.gov.

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to 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 www.lilly.com and www.lilly.com/newsroom/social-channels. 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, psoriasis and Crohn's disease, and reflects Lilly's current belief. As with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with the results to date, 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] What is Ulcerative Colitis? Crohn's and Colitis Foundation Website. http://www.crohnscolitisfoundation.org/what-are-crohns-and-colitis/what-is-ulcerative-colitis/. Accessed June 5, 2018.
[2] Adelphi Data 2017.

Refer to: Danielle Neveles, danielle.neveles@lilly.com; 317-796-4564 (Lilly media)
Brianna Wilkins; brianna.wilkins@edelman.com; 312-375-7495 (Media)
Kevin Hern; hern_kevin_r@lilly.com; 317-277-1838 (Lilly investors)

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