Mirikizumab Shows Continued Symptom Improvement and Reduction of Intestinal Inflammation in Patients with Crohn's Disease in 52-Week Phase 2 Trial

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– Results from the 52-week study showed continued symptom improvement and reduction of intestinal mucosal inflammation in patients with moderately to severely active Crohn's disease

– These Phase 2 data reinforce the continued evaluation of mirikizumab in the ongoing, pivotal VIVID Phase 3 program as a potential treatment for patients with Crohn's disease

INDIANAPOLIS, Oct. 12, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE:LLY) announced today new efficacy and safety data from the Phase 2 SERENITY study evaluating mirikizumab in patients with moderately to severely active Crohn's disease, a form of inflammatory bowel disease (IBD) that can cause systemic inflammation manifested as abdominal pain, diarrhea, fever, weight loss and lead to intestinal obstruction, fibrosis and other complications. SERENITY included a 12-week induction period and 40-week continued treatment period, which evaluated the safety and efficacy of multiple dosing regimens and two methods of administration through Week 52 as measured by endoscopic response, which reflects substantial reduction in inflammation of the lining of the bowel as seen during an endoscopy, and by Patient Reported Outcomes (PRO) remission, two important treatment goals in Crohn's disease. Detailed results from the trial are being presented virtually today in an abstract session at the United European Gastroenterology Week (UEG Week) 2020.

In the induction period, patients were randomized across four treatment arms to receive placebo or one of three doses of mirikizumab intravenously. At 12 weeks, patients who showed endoscopic improvement were randomized to continue mirikizumab treatment, administered either intravenously or subcutaneously. Patients who did not show endoscopic improvement or who had been randomized to the placebo arm in induction were assigned to receive mirikizumab treatment intravenously.

In the continued treatment period of the study, patients achieved key secondary outcomes at Week 52 including endoscopic response (defined as at least 50% reduction from baseline in Simple Endoscopic Score for Crohn's Disease [SES-CD]), PRO remission (defined as an average daily stool frequency of ≤2.5 and abdominal pain ≤1 and no worse than baseline) and endoscopic remission (defined as achieving an SES-CD score <4 for ileal-colonic disease or <2 for isolated ileal disease, and no subscore >1).

- **Endoscopic response:** Nearly 60% of patients achieved endoscopic response (58.5% in the randomized IV dosing group and 58.7% in the SC group).
- **PRO remission:** More than 45% of patients achieved PRO remission (46.3% in the IV group and 45.6% in the SC group).

"Crohn's disease is a serious and difficult-to-treat condition, and there is a significant need for additional treatments. I am encouraged by the results of this study, which showed response in both symptom relief and endoscopic response and remission at 52 weeks of treatment with mirikizumab," said Bruce E. Sands, MD, MS, 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.

Among the subset of patients who achieved endoscopic response at Week 12, 69.6% and 66.7% in the IV (n=23) and SC (n=24) groups, respectively, also had endoscopic response at Week 52. Additionally, among those with endoscopic remission at Week 12, 50.0% and 64.3% in the IV (n=6) and SC (n=14) groups, respectively, also had endoscopic remission at Week 52.

"People who live with moderate to severe Crohn's disease need additional treatment options and are looking for innovative therapies that can address their challenging and painful symptoms," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "With these encouraging Phase 2 results, we look forwarding to continuing our clinical program for mirikizumab with the hope that we can provide help for those living with Crohn's disease."

One patient in each group among those who showed endoscopic improvement at Week 12 discontinued due to an adverse event (AE). Similar frequencies of treatment-emergent AEs and serious AEs were reported in IV and SC groups. The most common treatment-emergent AEs reported were nasopharyngitis (4.9% in IV group, 13% in SC group), headache (7.3% in IV group, 8.7% in SC group) and arthralgia (joint pain) (7.3% in IV group, 13% in SC group).

At UEG Week, Lilly also virtually presented additional results for mirikizumab from the Phase 2 Crohn's disease study as well as data on bowel urgency and quality of life in patients with ulcerative colitis (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 Crohn's Disease
Crohn's disease, which is a form of inflammatory bowel disease (IBD), is a chronic immune-mediated condition of the gastrointestinal (GI) tract. Crohn's most commonly affects the end of the small bowel (the ileum) and the beginning of the colon, but it may affect any part of the GI tract, from the mouth to the anus. IBD, which is inclusive of Crohn's disease and ulcerative colitis, affects 10 million people worldwide.

About the Mirikizumab Phase 2 Trial in Crohn's Disease

SERENITY, the Phase 2, multi-center, randomized, parallel-arm, double-blind, placebo-controlled trial was designed to assess the safety and efficacy of mirikizumab in patients with moderately to severely active Crohn's disease. At baseline, participants were randomized with a 2:1:1:2 allocation across four treatment arms (mirikizumab 200 mg, mirikizumab 600 mg, mirikizumab 1000 mg, and placebo). The primary endpoint was endoscopic response as determined by the proportion of participants achieving at least 50 percent reduction from baseline on the Simple Endoscopic Score for Crohn's Disease (SES-CD) at Week 12. In May 2019, Lilly reported Phase 2 results showing more patients with moderate to severe Crohn's disease receiving mirikizumab achieved clinical remission and response at 12 weeks. Overall, the safety profile at 12 weeks was consistent with that of mirikizumab in studies of ulcerative colitis and with the class.

About Lilly in Immunology
Lilly is bringing our heritage of championing groundbreaking, novel science to immunology and is driven to change what's possible for people living with autoimmune diseases. There are still significant unmet needs, as well as personal and societal costs, for people living with a variety of autoimmune diseases and our goal is to minimize the burden of disease. Lilly is investing in leading-edge clinical approaches across its immunology portfolio in hopes of transforming the autoimmune disease treatment experience. We've built a deep pipeline and are focused on advancing cutting edge science to find new treatments that offer meaningful improvements to support the people and the communities we serve.

About Eli Lilly and Company
Lilly is a global healthcare 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 www.lilly.com and www.lilly.com/news. 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 moderate-to-severe plaque psoriasis, Crohn's disease and ulcerative colitis, 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 undertake no duty to update forward-looking statements to reflect events after the date of this release.

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