



Lilly Discloses First-in-Class, Interim Phase 2 Data in Pediatric Patients and New Analysis from Phase 3 Program in Adult Patients for Mirikizumab in Ulcerative Colitis

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- First interim Phase 2 data of an IL-23p19 antagonist in pediatric patients

- New analysis from the pivotal Phase 3 LUCENT-1 and LUCENT-2 studies

INDIANAPOLIS, May 9, 2023 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today new investigational data for mirikizumab in patients with moderately to severely active ulcerative colitis (UC) that further support the efficacy and safety seen in previous pivotal studies.

Data presented at Digestive Disease Week® (DDW), held in Chicago from May 6-9, include an oral presentation of an interim analysis of mirikizumab as induction therapy in pediatric patients with moderately to severely active UC from the Phase 2 SHINE-1 study, and a new analysis from LUCENT-1 and LUCENT-2 studies evaluating the relative association of bowel urgency remission on Inflammatory Bowel Disease Questionnaire (IBDQ) scores, which assess the impact of UC on quality of life in adults.

Interim Phase 2 Data from the First IL-23p19 Study in Pediatric Patients with UC

Lilly reported the first pharmacokinetic (PK), efficacy and safety data in 26 pediatric patients with moderately to severely active UC treated with mirikizumab. These interim results are from the Phase 2 SHINE-1 study (NCT04004611) and include data on all patients through induction at Week 12. The PK, safety and efficacy data were consistent with the adult Phase 3 LUCENT-1 study and support the planned pediatric Phase 3 studies in UC and Crohn's disease starting later this year. Importantly, this is the first data of any IL-23p19 antagonist in pediatric patients. Additional details on these results can be found in the abstract [here](#).

"Ulcerative colitis is a difficult-to-treat disease that can be particularly challenging for children and adolescents given the unpredictable and often burdensome symptoms that can impact them at a critical time in their development," said Marla Dubinsky, M.D., Professor of Pediatrics and Medicine, Co-director of the Susan and Leonard Feinstein IBD Clinical Center, Chief of the Division of Pediatric Gastroenterology and Nutrition at the Icahn School of Medicine at Mount Sinai. "This study provides the first data showing the potential of mirikizumab in the treatment of pediatric patients with UC and aligns with the clinical evidence we have seen for mirikizumab in adults. This is a promising step for children, adolescents and their families who to date have had limited treatment options to address this significant unmet need."

New Analysis from the Phase 3 LUCENT-1 and LUCENT-2 Studies in Adults with UC

In this new analysis, remission of key symptoms of UC, including bowel urgency, was associated with significant improvement in IBDQ total scores among adults treated with mirikizumab. Of those treated with mirikizumab at 12 and 52 weeks, bowel urgency remission directly accounted for a 44.8% and 32.5% improvement in IBDQ total score, respectively; 22.7% and 39.1% improvement, respectively, was mediated by rectal bleeding remission, and 32.5% and 28.4%, respectively, mediated by stool frequency remission. These findings suggest that bowel urgency is a critical and independent symptom that considerably impacts a patient's quality of life. More information can be found on this study in the abstract linked [here](#).

"Lilly's data at DDW support the strong clinical profile of mirikizumab as a potential treatment for people living with UC," said Lotus Mallbris, M.D., Ph.D., senior vice president of global immunology development and medical affairs at Lilly. "Taken together, these studies underscore Lilly's confidence in both the potential of mirikizumab as a treatment for ulcerative colitis and in delivering new treatment options for patients in the gastroenterology space."

Lilly will present a total of 11 abstracts at DDW, including four oral presentations, that reinforce its commitment to continued innovation for millions of people living with IBD. The studies, along with the times and abstract numbers for the sessions, are highlighted below. All times are listed in Central Daylight Time.

Mirikizumab (marketed as Omvoh® in Japan) was recently approved by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan and was given a positive recommendation by the Committee for Medicinal Products for Human Use (CHMP) from the European Medicines Agency. Lilly expects regulatory decisions in the European Union and additional markets around the world in 2023.

Lilly also expects to share topline data from its Phase 3 program for mirikizumab in Crohn's disease later this year.

Oral Presentations

- A Transcriptome-Dependent Prognostic Model of Response in Patients with Ulcerative Colitis (Sunday, May 7; 4:30 – 4:45 p.m. Presenting author: Venkatesh Krishnan) Abstract: 569
- PK, Efficacy and Safety of Mirikizumab as Induction Therapy in Pediatric Patients with Moderately to Severely Active Ulcerative Colitis: Results from the Phase 2 SHINE-1 Study (Monday, May 8; 2:15 – 2:30 p.m. Presenting author: Jess L. Kaplan) Abstract: 781
- Bowel Urgency Outcomes are Associated with Improvement in Fatigue in Patients with Moderately-to-Severely Active Ulcerative Colitis: A Pooled Analysis of LUCENT-1 and LUCENT-2 Phase 3 Trials (Tuesday, May 9; 8:30 – 8:45 a.m. Presenting author: David T. Rubin) Abstract: 963
- United States and European Patient Perspectives on the Impact of Moderate-to-Severe Ulcerative Colitis on Sexual

Activity: Communicating Needs and Features of IBD Experiences (CONFIDE) Survey (Tuesday, May 9; 2:15 – 2:30 p.m.
Presenting author: Marla C. Dubinsky) Abstract: 1139

Poster/ePoster Presentations

- Mirikizumab Pharmacokinetics and Exposure-Response Relationships in Patients with Moderately to Severely Active Ulcerative Colitis: Results from Randomised Phase 2 and Phase 3 Induction and Maintenance Trials (Saturday, May 6; ePoster. Presenting author: Xin Zhang) Abstract: EP145
- Relative Association of Bowel Urgency Clinically Meaningful Improvement or Bowel Urgency Remission vs. Stool Frequency Remission and Rectal Bleeding Remission with Improvement in IBDQ Scores: Results from LUCENT-1 and LUCENT-2 (Sunday, May 7; 12:30 – 1:30 p.m. Presenting author: Bruce E. Sands) Abstract: Su1796
- Treatment Satisfaction Among Ulcerative Colitis Patients with and without Bowel Urgency – A Global Real-World Analysis (Sunday, May 7; 12:30 – 1:30 p.m. Presenting author: Theresa Hunter Gobble) Abstract: Su1801
- Early Histo-Endoscopic Response at Week 12 Predicts Clinical Outcomes at Week 52 with Mirikizumab in Ulcerative Colitis LUCENT Trials (Monday, May 8; 12:30 – 1:30 p.m. Presenting author: Fernando Magro) Abstract: Mo1735
- Extended Induction Response in Patients Treated with Mirikizumab with Moderately to Severely Active Ulcerative Colitis in LUCENT Trials (Tuesday, May 9; 12:30 – 1:30 p.m. Presenting author: Geert D'Haens) Abstract: Tu1706
- Effect of Mirikizumab on Clinical and Endoscopic Outcomes based on Prior Advanced Therapy Failure in Patients with Moderately to Severely Active Ulcerative Colitis (Tuesday, May 9; 12:30 – 1:30 p.m. Presenting author: Seyedehsan Navabi) Abstract: Tu1712
- Fully Automated Histological Classification of Cell Types and Tissue Regions of Celiac Disease is Feasible and Correlates with The Marsh Score (Tuesday, May 9; 12:30 – 1:30 p.m. Presenting author: Aaron M. Gruver) Abstract: Tu1352

About Mirikizumab

Mirikizumab is an interleukin-23p19 antagonist being studied for the potential treatment of moderately to severely active ulcerative colitis. Mirikizumab selectively targets the p19 subunit of IL-23 and inhibits the IL-23 pathway. Inflammation due to over-activation of the IL-23 pathway plays a critical role in the pathogenesis of UC.

About Lilly

Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 51 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit [Lilly.com](https://www.lilly.com) and [Lilly.com/newsroom](https://www.lilly.com/newsroom) or follow us on [Facebook](https://www.facebook.com/lilly), [Instagram](https://www.instagram.com/lilly), [Twitter](https://twitter.com/lilly) and [LinkedIn](https://www.linkedin.com/company/lilly). P-LLY

About Digestive Disease Week®

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from May 6-9, 2023. The meeting showcases more than 3,100 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

Disclosure: Dr. Dubinsky has provided paid consulting and advisory services to Eli Lilly and Company and participates on the steering committees for the mirikizumab program.

Cautionary Statement Regarding Forward-Looking Statements

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 people with moderately to severely active ulcerative colitis and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study results to date, or that mirikizumab will receive FDA and other additional regulatory approvals, or that it will be commercially successful. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's 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.

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SOURCE Eli Lilly and Company