

Sorriso Pharmaceuticals Announces Positive Phase 1b Clinical Trial Results for SOR102 in Ulcerative Colitis

Data from Dual-Acting Oral Biologic Show Promising Safety and Efficacy Profile

Topline Clinical Data Demonstrates Activity of SOR102 Across Multiple Clinical Endpoints Supporting Advancement to Phase 2 Development

SALT LAKE CITY--([BUSINESS WIRE](#))--Sorriso Pharmaceuticals, a biopharmaceutical company developing novel orally dosed antibodies for immune-mediated disease, today announced positive results from its Phase 1b clinical trial evaluating SOR102, an oral, dual-acting biologic targeting TNF α and IL-23, in patients with ulcerative colitis (UC). The study met its primary objectives, demonstrating a favorable safety and tolerability profile. Additionally, key exploratory efficacy endpoints showed promising activity of SOR102 across multiple clinical endpoints. This is the first successful demonstration of an orally dosed antibody delivering clinical efficacy.

"Our Phase 1b results with SOR102 mark a significant milestone for Sorriso Pharmaceuticals and the field of autoimmune therapeutics," said Ciara Kennedy, Chief Executive Officer of Sorriso Pharmaceuticals. "We believe SOR102, a first-in-class, oral biologic that inhibits TNF α and IL-23, two validated pathways in inflammatory bowel disease, will be a game changer. These clinical data for SOR102 provide strong evidence for its potential to provide an effective and convenient oral treatment option for patients living with ulcerative colitis. We are excited to advance SOR102 into Phase 2 development."

The randomized, double-blind, placebo-controlled trial enrolled 22 patients across 2 sites. Patients were randomized to receive one of two SOR102 doses or placebo for 6 weeks. The study assessed safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary efficacy. Among patients who completed the study, those in the high-dose SOR102 group achieved statistically significant separation from placebo across multiple clinical endpoints, including Mayo Score clinical response, modified Mayo Score clinical response, symptomatic remission, and mean decreases from baseline in Mayo Score, modified Mayo Score, and UC-100 score.

Based on these results, Sorriso Pharmaceuticals plans to initiate a Phase 2 clinical trial in 2025, further evaluating SOR102 in a larger patient population. "Ulcerative colitis remains a challenging condition, but we have seen promising rates of clinical remission from dual inhibition of TNF α and IL-23 using systemically delivered antibodies," said Carlos Sattler, Chief Medical Officer of Sorriso Pharmaceuticals. "These results, observed after just six weeks of treatment, compare favorably to approved treatments and underscore SOR102's potential to redefine the treatment paradigm by targeting these two critical inflammatory pathways with a convenient oral therapeutic."

Dr. Vipul Jairath, Professor of Medicine at Western University, Canada and Chair of Sorriso Pharmaceuticals' Scientific Advisory Board, added, "As a clinician and researcher, I'm thrilled to see the progress SOR102 is making in addressing the complex pathophysiology of ulcerative colitis. The dual inhibition of TNF α and IL-23 with an orally administered product is a bold and innovative approach that holds great promise for transforming patient care. These Phase 1b results provide a strong foundation for further development and underscore the potential of Sorriso's platform to deliver groundbreaking oral therapies."

The detailed study results will be presented at the upcoming 20th Congress of ECCO, to be held in Berlin, Germany from February 19 to 22, 2025.

About SOR102

SOR102, an oral biologic, simultaneously inhibits TNF α and IL-23(p19), two clinically validated drivers of inflammatory bowel disease (IBD), providing combination therapy locally within inflamed tissue with minimal systemic exposure. This dual targeting approach may increase efficacy through simultaneous blockade of different mechanisms of IBD.

About Sorriso Pharmaceuticals

Sorriso Pharmaceuticals is a biopharmaceutical company advancing a pipeline of disease-modifying antibodies for the treatment of immune-mediated diseases, including ulcerative colitis and Crohn's disease. The Sorriso platform generates potent antibodies that can be delivered orally and are designed to maintain activity throughout human intestinal tissue. For more information, please visit www.sorrisopharma.com

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