

Sorriso Pharmaceuticals Presents Positive SOR102 Phase 1b Ulcerative Colitis Data at ECCO Conference

Data from Oral Biologic Show Promising Safety and Efficacy; SOR102 Activity Across Multiple Endpoints Supports Phase 2 Development

SALT LAKE CITY, UT, UNITED STATES, February 27, 2025 /EINPresswire.com/ -- Sorriso Pharmaceuticals, a biopharmaceutical company developing novel orally dosed antibodies for immune-mediated disease, today announced the presentation of Phase 1b clinical data from of SOR102, its first-in-class oral biologic targeting TNF α and IL-23p19, in patients with ulcerative colitis (UC) at the 2025 European Crohn's and Colitis Organisation (ECCO) Annual Congress in Berlin, Germany.

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 data showed significant clinical improvements in patients with moderate-to-severe UC, highlighting the potential of Sorriso's oral biologic as a transformative treatment option for those suffering from this debilitating condition. Furthermore, as the first oral biologic with activity against both TNF α and IL-23p19, key drivers of inflammation in UC, SOR102 has the potential to provide a novel therapeutic approach for UC patients, many of whom face limited options for effective treatment.

Key findings from the Phase 1b trial include:

- **Safety Profile:** SOR102 exhibited a favorable safety profile, with adverse events predominantly mild to moderate in severity; no new safety signals were observed.
- **Efficacy Results:**
 - **Clinical Response:** In the intent-to-treat (ITT) analysis, Mayo Score and modified Mayo Score clinical response were 56% and 67% in the high-dose SOR102 group compared to 17% and 33% in the placebo group, respectively. In the Per Protocol analysis, Mayo Score and modified Mayo Score clinical response were both 100% in the high-dose SOR102 group compared to 17% and 33% in the placebo group, respectively. Both results were statistically significant ($p \leq 0.003$).
 - **Symptomatic Remission:** In the ITT analysis, symptomatic remission was achieved in 56% of the patients in the high-dose SOR102 group compared to 0% of patients in the placebo group ($p = 0.044$). In the Per Protocol analysis, symptomatic remission was achieved in 100% of the patients in the high-dose SOR102 group compared to 0% of patients in the placebo group.

(p=0.002).

o Endoscopic improvement was observed in 22% of patients in the high-dose SOR102 group compared to 0% of patients in the placebo group. In the Per Protocol analysis, endoscopic improvement was observed in 40% of patients in the high-dose SOR102 group compared to 0% of patients in the placebo group.

o In the ITT population, the mean change from baseline in UC-100 score in the high-dose SOR102 group was -18.1 compared to -8.5 in the placebo group. In the Per Protocol population, the mean change from baseline in UC-100 score in the high-dose SOR102 group was -32.6 compared to -8.5 in the placebo group (p=0.03).

“We are excited to present these promising Phase 1b results at ECCO, which show that our first-in-class oral biologic has the potential to offer substantial clinical benefits for UC patients,” said Ciara Kennedy, CEO of Sorriso. “The data reflect not only robust efficacy in reducing disease activity but also demonstrate the convenience of an oral formulation, which may improve patient adherence and quality of life. These results strengthen our commitment to advancing this promising candidate into later-stage clinical trials.”

Sorriso is advancing SOR102 into Phase 2 trials, expected to begin later this year. The company remains focused on addressing the unmet needs of patients with autoimmune diseases and is dedicated to developing innovative, next-generation therapies for chronic conditions like UC.

The presentation at ECCO was delivered by Dr. Vipul Jairath during the Hot Topics plenary session on Saturday February 22nd. The SOR102 Phase 1b study abstract was selected amongst the top 10 oral abstracts of ECCO 2025, highlighting it as one of the most important scientific insights presented at the conference. For additional information and to view the data presented, please visit the ECCO website or contact Sorriso’s communications team.

SOR102, an oral biologic, simultaneously inhibits TNF 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.

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

1. Mayo Score clinical response: decrease from study baseline total Mayo score of ≥3 points and ≥30%, plus a decrease in rectal bleeding subscore of ≥1 point or an absolute rectal bleeding subscore of 0 or 1; modified Mayo Score clinical response: decrease from study baseline total

Mayo score of ≥ 2 points and $\geq 30\%$, plus a decrease in rectal bleeding subscore of ≥ 1 point or an absolute rectal bleeding subscore of 0 or 1

2. Symptomatic remission: Mayo stool frequency subscore of 0 or 1 without worsening, and Mayo rectal bleeding subscore of 0

3. Endoscopic improvement: Mayo endoscopic score of 0 or 1

4. UC-100 Score: a composite measure of disease activity calculated from the weighted sum of the Mayo stool frequency subscore, Mayo endoscopic score, and Robarts Histological Index; ranges from 1 to 100 with a higher score denoting greater disease activity (Jairath V et al. Lancet Gastroenterol Hepatol 2019;4:63–70).

Carolyn Coglianese

Sorriso Pharmaceuticals

ccoglianese@sorrisopharma.com

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