Final Safety, Pharmacokinetic and Pharmacodynamic Data from COL-5671 Phase 1 Clinical Study Presented at UEGW

COL-5671, a highly selective oral SIK3 inhibitor, demonstrated a favorable safety and pharmacokinetic (PK) profile

Pharmacodynamic (PD) data indicate potent TNFα suppression at low doses, with even greater IL-23 suppression observed in cellular systems.

Phase 2 moderate to severe psoriasis study to start recruitment in Q4 2026

Leuven, Belgium. October 19, 2026. Coultreon Biopharma, a clinical-stage immunology biotechnology company focused on transforming patients' lives through best-in-class medicines, today announced results from its completed Phase 1 study of COL-5671. The data are being presented at the 2026 United European Gastroenterology Week (UEGW) in Barcelona, Spain.

In this study, COL-5671 was well tolerated with a favorable safety profile across all doses evaluated in healthy volunteers treated for up to 14 days. The PK data demonstrated a highly favorable profile, with a long half-life, low interparticipant variability, and a strong dose–exposure relationship. PD assessment of COL-5671's ability to inhibit TNFα release in blood samples from dosed participants demonstrated that COL-5671 is a highly potent inhibitor, achieving TNFα inhibition comparable to that of monoclonal antibodies. Consistent with these findings, data from the multiple ascending dose (MAD) 15mg cohort demonstrated potent and sustained TNFα inhibition that remained above 90% at 24 hours. Doses of up to 40 mg were evaluated across the MAD cohorts.

COL-5671 inhibits the pathogenic cytokines IL-23 and IL-12 in human myeloid cells with even greater potency than TNFα and is predicted to achieve excellent tissue penetration. Together, these attributes support its strong therapeutic potential in ulcerative colitis, Crohn's disease, psoriasis, psoriatic arthritis, hidradenitis suppurativa, and other inflammatory diseases.

"We are delighted with the progress of COL-5671 since it entered the clinic in September 2025," said Pierre Raboisson, PhD, CEO and Founder of Coultreon Biopharma. "COL-5671 continues to generate exceptional data and has significant potential to transform the lives of patients with debilitating inflammatory diseases. We expect to begin recruiting shortly for our first patient study, a Phase 2 trial in psoriasis. We look forward to sharing further updates as the program advances."

Details of the poster presentation

Poster number: PP1210
Title: Safety, Pharmacokinetics and Pharmacodynamics from a Phase 1a study of COL-5671, a First-in-Class SIK3 Inhibitor that Suppresses TNFα, IL-23 and IL-12
Link to poster: https://www.coultreon.com/news

About COL-5671
COL-5671 was developed based on more than 12 years of preclinical and clinical research on SIK inhibitors for autoimmune diseases. COL-5671 is a highly selective SIK3 inhibitor designed to avoid the toxicities associated with SIK1 and SIK2 inhibition. It does not inhibit other kinases and has demonstrated a favorable profile in an extensive safety panel. Preclinical studies demonstrate that COL-5671 suppresses the release of the pro-inflammatory cytokines TNFα and IL-23 while promoting the release of the immunomodulatory cytokine IL-10. Together with findings from animal models of autoimmune disease, these results support the potential of COL-5671 as a treatment for ulcerative colitis, Crohn's disease, psoriasis, psoriatic arthritis, and hidradenitis suppurativa and other inflammatory diseases.

About the Phase 1 trial of COL-5671
The first-in-human study evaluated COL-5671 in healthy volunteers using single ascending dose (SAD) and multiple ascending dose (MAD) cohorts. In addition to characterizing safety and pharmacokinetics, the study incorporates extensive biomarker assessments to elucidate how COL-5671 modulates immune responses. The findings will guide the design of subsequent patient trials across multiple autoimmune diseases, which are planned to begin in 2026.

About Coultreon Biopharma
Coultreon Biopharma is developing best-in-class therapies targeting clinically validated pathways across immunology and metabolic diseases. The company leverages deep expertise in disease biology, drug discovery, and translational science to select the optimal therapeutic modality to address underlying disease biology with best-in-class therapies. Coultreon's pipeline is anchored by its leadership in salt-inducible kinase (SIK) biology, with a focus on selectively modulating key inflammatory pathways to deliver broader and more durable disease control. Its lead program, COL-5671, is a highly selective SIK3 inhibitor in clinical development for autoimmune diseases, with potential applicability across multiple immune-mediated conditions. For more information, visit http://www.coultreon.com or follow us on LinkedIn.