O3R-5671 Pharmacokinetic and Pharmacodynamic Data to be Presented at ECCO and Dosing in Final Cohort in First-in-human study initiated

Data from the first in human study on O3R-5671's potent TNFα inhibition

Studies in ulcerative colitis and psoriasis to initiate in H2 2026

Leuven, Belgium. February 20, 2025. Onco3R Therapeutics, a clinical-stage immunology and oncology biotech company dedicated to transforming patients' lives with best-in-class medicines, today announced the data to be presented in a poster presentation at the 21st congress of the European Crohn's and Colitis Organization (ECCO) taking place in Stockholm, Sweden from February 18-21.

The pharmacokinetic (PK) data generated in the first-in-human study demonstrates a highly attractive PK profile with a long half-life, low interpatient variability and highly correlative dose-exposure relationship. Pharmacodynamic (PD) data on O3R-5671's ability to inhibit TNFα release in the blood of dosed participants indicate that it is a highly potent inhibitor with the ability to inhibit TNFα as efficiently as monoclonal antibodies. Data from the 15mg MAD cohort demonstrate that O3R-5671 is able to potently inhibit TNFα in a sustained manner. At 24 hours, TNFα inhibition remains greater than 90%.

As O3R-5671 has the ability to inhibit the pathogenic cytokines IL-23 and IL-12 in human myeloid cells even more potently than it inhibits TNFα and is predicted to have excellent tissue penetration, it is a highly attractive molecule for development in ulcerative colitis, Crohn's disease, psoriasis, psoriatic arthritis and a variety of other indications.

The first-in-human study from which the PK and PD data described above were derived is investigating single and multiple ascending doses of O3R-5671 in healthy volunteers. Four single ascending dose (SAD) cohorts, including a cohort that assessed the effect of food on PK, have also been completed. In each of the SAD cohorts, subjects received a single oral dose of O3R-5671 between 5mg - 35mg. In the MAD cohorts, subjects receive O3R-5671 once a day for 14 days. Three MAD cohorts have been completed (5 mg, 10mg and 15mg). O3R-5671 had been safe and well tolerated to date, and a protocol amendment has been approved that will allow the exploration of higher doses in SAD and MAD cohorts.

"We are delighted with the progress we have made with O3R-5671 since entering the clinic in September of 2025" said Pierre Raboisson, PhD, CEO and Founder of Onco3R Therapeutics. "O3R-5671 continues to deliver exceptional data, and we are very excited about continuing its clinical development with patient studies planned to commence later this year. There is a strong scientific rationale that O3R-5671 will have activity in a variety of autoimmune diseases, and we plan on focusing on ulcerative colitis and psoriasis in the first instance before expanding into additional indications."

Dr. Raboisson added "In addition to our progress with the first-in-human study, we are also generating toxicology and manufacturing data that will allow us to submit clinical trial applications this summer with a view to initiating our patient studies shortly thereafter. O3R-5671 has the potential to make significant improvements to the lives of patients living with autoimmune diseases and we are highly motivated to drive its development so it can achieve its potential."

Details of the poster presentation

Poster number: P0932
Title: The First-in-Class SIK3 Inhibitor O3R-5671 Demonstrates Optimal Pharmacokinetics and Potent and Sustained Pharmacodynamic Activity in Human Participants
Presentation time: 1240 – 1340 CET
Presenter: Fabrice Kolb
Link to poster

About O3R-5671
O3R-5671 has been designed based on more than 12 years of preclinical and clinical data on SIK inhibitors for autoimmune diseases. O3R-5671 is a highly selective SIK3 inhibitor, which has been designed to avoid the toxicities associated with inhibiting SIK1 and SIK2. Furthermore, O3R-5671 does not inhibit other kinases and has demonstrated a highly attractive profile in an extensive safety panel. Preclinical data demonstrated that O3R-5671 inhibits the release of the pro-inflammatory cytokines TNFα and IL-23 and promotes the release of the immunomodulatory cytokine IL-10. These data, along with data from animal models of autoimmune diseases, indicate that O3R-5671 has the potential to treat a variety of autoimmune diseases including ulcerative colitis, Crohn's Disease, psoriasis, psoriatic arthritis and rheumatoid arthritis.

About the Phase 1 trial of O3R-5671
The first-in-human is evaluating O3R-5671 in healthy volunteers using a single ascending dose (SAD) and multiple ascending dose (MAD) design. In addition to assessing safety and pharmacokinetics, the trial includes extensive biomarker tests that will provide insights into how O3R-5671 modulates immune responses. The results from the trial will inform the design of subsequent patient trials across a range of autoimmune diseases, which are planned to commence in 2026.

About Onco3R Therapeutics
At Onco3R Therapeutics, we are driven by our purpose to transform the lives of patients with autoimmune diseases and cancer through precision-designed, best-in-class therapies. With over 150 years of combined R&D experience, our team brings deep expertise in disease biology, drug discovery & development, and translational science. We focus on clinically validated targets and select the right therapeutic modality, small or large molecules, to address the underlying disease biology with best-in-class therapies. Our mission is to develop safer, more effective medicines in oncology and immunology that truly make a difference for patients. By integrating learnings from past clinical challenges and applying cutting-edge technologies, we aim to de-risk clinical development and accelerate the delivery of innovative treatments with real-world impact. The company is based in the biotech cluster in Leuven, Belgium. For more information, visit www.onco3r.com or follow us on LinkedIn.