

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 TNF α inhibition to be presented

Dosing of the final cohort in the first in human study has been initiated

Studies in ulcerative colitis and psoriasis to initiate in H2 2026

Leuven, Belgium. January 09, 2025. Onco3R Therapeutics, a clinical-stage immunology and oncology biotech company dedicated to transforming patients' lives with best-in-class medicines and leader in selective SIK3 inhibitor development, today announced the acceptance of an abstract for presentation at the 21st congress of the European Crohn's and Colitis Organization (ECCO), which will take place in Stockholm, Sweden from February 18-21. In addition, Onco3R announced that dosing in the final cohort of the first-in-human study of O3R-5671 has been initiated.

The pharmacokinetic (PK) data generated in the first-in-human study demonstrate a highly attractive, flat 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 TNF α release in the LPS-stimulated blood of dosed participants indicate that it is a potent inhibitor with the ability to inhibit circulating TNF α as efficiently as approved monoclonal antibodies. As O3R-5671 has demonstrated the ability to inhibit the pathogenic cytokines IL-23 and IL-12 in human myeloid cells even more potently than it inhibits TNF α , it is a very attractive oral drug candidate 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 have already been completed. In each of the SAD cohorts, subjects received a single oral dose of O3R-5671 of between 5mg - 35mg. In the Multiple Ascending Dose (MAD) cohorts, subjects received O3R-5671 once a day for 14 days. To date, two MAD cohorts have been completed (5mg and 10mg) and dosing of the third MAD cohort (15mg) commenced earlier this week. Based on the current protocol, the 15mg MAD cohort is expected to be the final cohort in the study.

"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 broad variety of autoimmune diseases, and we plan to on focus on ulcerative colitis and psoriasis in the first instance before expanding into a variety of other 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."

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 TNF α 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 study 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](#).