Onco3R Therapeutics Announces Completion of First Cohort in Phase 1 Trial of Novel SIK3 inhibitor O3R-5671 and Oral Presentation at UEGW 2025

Dosing of first cohort in Phase 1 trial of O3R-5671 complete with no adverse findings

On track for full data read out in the first half of 2026

Discovery and preclinical data on O3R-5671 selected for oral presentation at United European Gastroenterology Week 2025

Leuven, Belgium. October 6, 2025. Onco3R Therapeutics, a clinical-stage immunology and oncology biotech company dedicated to transforming patients' lives with best-in-class medicines, today announced the successful completion of dosing of the first cohort of subjects in the Phase 1 trial of its novel SIK3 inhibitor O3R-5671. Dosing of subjects in the second cohort investigating a higher dose of O3R-5671 is underway.

In this first cohort, six subjects received a dose of 5mg O3R-5671. Pharmacokinetic and safety data support investigating a higher dose in the second cohort of the study, which is in progress.

The company also announced that discovery and preclinical data on O3R-5671 will be the focus of an oral presentation in today's Late-Breaker Session at the United European Gastroenterology Week (UEGW) 2025, taking place in Berlin and online, October 4-7. UEG Week is the largest gastroenterology conference in Europe and one of the leading meetings worldwide. It brings together gastroenterology experts, physicians, researchers, and industry representatives from around the globe to share the latest research advances, clinical practices, and treatment solutions.

Preclinical data from various *in vitro* models demonstrate that O3R-5671 potently inhibits TNFα, IL-12, and IL-23 release and induces IL-10. Furthermore, O3R-5671 demonstrated efficacy in animal models of inflammatory bowel disease (IBD) and psoriasis similar to treatments used as standard of care for both diseases. The predicted pharmacokinetic profile of O3R-5671 based on preclinical studies is expected to be conducive to potent SIK3 inhibition and clinical efficacy in patients with IBD and psoriasis. Dr. Fabrice Kolb, Onco3R's Head of Immunology will present a summary of these findings during today's presentation.

"Many patients with autoimmune diseases relapse or cannot tolerate existing therapies. With O3R-5671, we aim to develop an effective and well-tolerated oral treatment," said Pierre Raboisson, PhD, CEO and Founder of Onco3R Therapeutics. "Dosing completion of the first cohort in our first-in-human trial marks an important step forward in this research. In this group, we observed no clinically significant safety findings, and the pharmacokinetics were consistent with our expectations. We are proud of this milestone and remain on track to complete the trial, with final results anticipated in the first half of 2026."

He added, "Being selected for an oral presentation in the Late-Breaker Session at one of the leading gastroenterology conferences highlights the strong interest in this program. We look forward to sharing key preclinical findings on O3R-5671 and engaging with experts in the field."

Presentation details
Title: Discovery of a Novel, Selective SIK3 inhibitor for the Treatment of Ulcerative Colitis, Crohn's Disease and Other Autoimmune Diseases
Session: Hot off the Press: IBD treatment (Late Breakers)

Session Time: 10:00-11:00 CET
Presentation Time: 10:24-10:36
Location: Room Helsinki
Presenting author: Fabrice Kolb, PhD

UEGW abstracts are available on the UEGW website and the slides from Dr. Kolb's presentation are available at www.onco3r.com.

About O3R-5671

O3R-5671 has been ~~designed~~ developed based on more than 12 years of preclinical and clinical data on SIK inhibitors for autoimmune diseases. O3R-5671 is 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 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.

Commented [MV1]: Suggestion to avoid using 'designed' twice in the same section

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.