

Onco3R Therapeutics Announces Approval of First Clinical Trial Application for Novel SIK3 inhibitor O3R-5671 in Autoimmune Diseases

O3R-5671 is designed to overcome the limitations of first-generation SIK inhibitors, providing a potential new oral treatment option for multiple autoimmune diseases

Clinical Trial Application approval marks Onco3R's transition into a clinical-stage company

Leuven, Belgium. September 4, 2025. Onco3R Therapeutics, a clinical-stage immunology and oncology biotech company dedicated to transforming patients' lives with best-in-class medicines, today announced the approval of a Clinical Trial Application (CTA) by the Belgian regulatory authorities for its SIK3 inhibitor O3R-5671. The trial will be conducted at the SGS Clinical Pharmacology Unit in Antwerp, a leading clinical research center in Belgium.

O3R-5671 has been developed based on more than 12 years of preclinical and clinical data on SIK inhibitors for autoimmune diseases, and is expected to have applications across a broad range of conditions, including ulcerative colitis, Crohn's disease, psoriasis, psoriatic arthritis, and rheumatoid arthritis. Preclinical data show that O3R-5671 has an Improved toxicity profile, enhanced efficacy, and greater SIK isoform specificity, thereby overcoming the key shortcomings that hindered the development of first-generation SIK inhibitors for autoimmune diseases.

The first-in-human trial will evaluate 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.

"At Onco3R, we are dedicated to improving patients' lives through best-in-class medicines and by building a deep pipeline in immunology and oncology," said Pierre Raboisson, PhD, CEO and Founder of Onco3R Therapeutics. "We are very excited to achieve this significant milestone, marking our transition into a clinical-stage company with the initiation of our first clinical trial. While effective therapies exist for many autoimmune diseases, too many patients relapse or cannot tolerate treatments due to toxicities. With O3R-5671, we believe we are uniquely positioned to develop a well-tolerated, effective, and convenient oral therapy for these patients, and we look forward to advancing the program."

The first-in-human trial is expected to start enrolling subjects over the coming weeks, with dosing of the first subject anticipated later in September. Final data from the study are expected to be available in the first half of 2026.

About O3R-5671

O3R-5671 is a targeted SIK3 inhibitor which has been designed to avoid the toxicities associated with inhibiting SIK2 and SIK1. 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 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 and a very attractive pharmacokinetic profile, 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 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 multidisciplinary 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 immunology and oncology 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. Onco3R Therapeutics is based in the biotech cluster in Leuven, Belgium. For more information, visit www.onco3r.com or follow us on [LinkedIn](#).

For further information, please contact:
contact@onco3r.com