Press Release
Munich, Germany, June 12, 2024

SciRhom Announces Approval of First Clinical Trial Application for a Novel iRhom2-targeting Antibody Against Autoimmune Diseases.

Munich, Germany, June 12, 2024 – SciRhom GmbH, a biopharmaceutical company pioneering the development of first-in-class therapeutic antibodies, announced today the approval of a clinical trial application (CTA) by the Austrian regulatory authorities (BASG/AGES) for its development program SR-878. The upcoming clinical study aims to evaluate safety in healthy volunteers for the proprietary iRhom2-targeting monoclonal antibody SR-878 and provide initial evidence of clinical activity in a second part of the study. SciRhom expects to initiate the first dosing of study participants in the second half of 2024.

„We are entering a transformative period for SciRhom with our first-in-class antibody program SR-878 accelerating towards clinical studies. In parallel to transitioning into a clinical-stage drug development organization, SciRhom has established a comprehensive preclinical pharmacology and toxicology data package for the lead development program, a robust and efficient manufacturing process, and secured broad patent protection for iRhom2-targeting therapeutic strategies", commented Dr. Jan Poth, Managing Director & CEO of SciRhom.

„Today's news is a testament to the high-quality standards and joint efforts invested by SciRhom's team and our network partners over an extended period of time. The resulting CTA package built the basis for a productive interaction with the regulatory authorities and its approval brings us one step closer to evaluating our first therapeutic candidate in human studies. I want to thank everyone who has contributed to this development milestone", added Dr. Jens Ruhe, Managing Director & COO of SciRhom.

The target molecule iRhom2 acts as a crucial regulator of TACE/ADAM-17, a master switch for various disease-relevant signaling pathways. SR-878 was designed to simultaneously block several of these pathways, including TNF-alpha and IL-6R signaling. In preclinical models of rheumatoid arthritis (RA) and inflammatory bowel disease (IBD), SR-878 has demonstrated its ability to inhibit TACE activity potently and selectively in immune cells, facilitating tissue regeneration and immune re-balancing. In these preclinical studies, SR-878 as a monotherapy showed superior preclinical efficacy over individually used approved drugs for autoimmune disorders. Moreover, the toxicological assessment of SR-878 supported the expected favorable safety profile of the approach.

About iRhom2

TACE (TNF-alpha converting enzyme, also known as ADAM-17) controls several major signaling pathways, including TNF-alpha, IL-6R, and EGFR signaling. TACE is therefore widely accepted as a potential target to block pro-inflammatory pathways, but direct inhibition of TACE causes severe side effects. The more recent discovery that iRhom2 (inactive Rhomboid 2, RHBDF2) simultaneously regulates the TACE-dependent release of TNF-alpha and of other pro-inflammatory molecules from immune cells provides the exciting opportunity to target the pro-inflammatory activities of TACE, while preserving its other vital functions. Given the pivotal role of iRhom2, numerous new research studies have recently highlighted the therapeutic potential of targeting iRhom2 to treat immunological and inflammatory diseases and beyond, including oncological, infectious and metabolic diseases.

About SciRhom

At SciRhom, we are translating world-leading expertise in the TACE/ADAM-17 pathway and its central role in autoimmunity and other indications into breakthrough biopharmaceuticals. We are developing proprietary and first-in-class iRhom2-targeting therapies and are accelerating our lead antibody program SR-878 into and through clinical development.

For further information, please visit www.SciRhom.com

Contact

SciRhom GmbH
Dr. Jan Poth (Managing Director & CEO)
Email: info@SciRhom.com

Valency Communications
Mario Brkulj
Email: mbrkulj@valencycomms.eu