

SciRhom Files Clinical Trial Application for First-in-Human Trials of Novel Antibody Against Autoimmune Diseases.

Munich, Germany, November 15, 2023 – SciRhom GmbH, a pioneering biotech enterprise specialized in developing first-in-class therapeutic antibodies, announced today the achievement of a significant milestone in its development pipeline. The company has submitted a Clinical Trial Application for its lead candidate, SR-878, a groundbreaking antibody designed to target iRhom2 as a therapeutic strategy for numerous autoimmune disorders.

Dr. Jan Poth, Managing Director & CEO of SciRhom, expressed his gratitude and pride in the development team's outstanding efforts, stating, *„We can be proud of what was achieved, and a big thank you goes to our entire team. This milestone allows us to evaluate our promising approach in humans, bringing us one step closer to our ultimate goal of helping patients suffering from autoimmune diseases.“*

iRhom2 is a critical regulator of the enzyme TACE, a master switch for various disease-causing signaling pathways. SR-878, the company's internal code for their lead iRhom2 antibody, simultaneously blocks several of these pathways, among them TNF- α and IL-6R signaling, which are currently targeted individually by drugs approved for autoimmune disorders. Moreover, SR-878 facilitates tissue regeneration and immune re-balancing.

Preclinical studies demonstrated the superior efficacy and likely favorable safety profile of SR-878. Results from both *in vitro* and *in vivo* models of rheumatoid arthritis (RA) and inflammatory bowel disease (IBD) revealed that SR-878 potently and selectively inhibits TACE in immune cells, offering protection against these debilitating conditions. Lupus nephritis and dermatological diseases are further leading indications in SciRhom's development pipeline.

SciRhom has worked to unravel the complexities surrounding iRhom2 that make it a challenging target for antibody development. The submission of the Clinical Trial Application marks the successful completion of that endeavor and all necessary preclinical work packages. Collaborating with WuXi Biologics, the company established a robust biopharmaceutical manufacturing process that consistently produces high yields of SR-878 with excellent antibody properties and remarkable quality. The toxicological characterization of SR-878 confirmed its expected favorable safety profile, with no adverse findings in the 4-week GLP toxicity study.

The company's collaboration with external partners was instrumental in reaching this pivotal stage. Dr. Jens Ruhe, Managing Director & COO of SciRhom, emphasized the highly satisfactory teamwork: *„The collaborative achievement of our team and expert advisors with WuXi Biologics and other vendors not only underscores the power of teamwork but also exemplifies the remarkable synergy and seamless cooperation of a harmonious and reliable partnership. All parties have been truly exemplary, and we couldn't be more satisfied with the results of our combined efforts.“*

Submission of the Clinical Trial Application paves the way to initiate the first clinical study of SR-878 in humans and is a testament to the company's unwavering commitment to creating game-changing treatments.

About iRhom2

TACE (TNF-alpha converting enzyme or ADAM17) controls several major signaling pathways, including TNF-alpha, IL-6, and EGFR signaling. TACE has therefore been considered a potential target to block pro-inflammatory pathways, but direct inhibition of TACE causes severe side effects, such as skin and intestinal lesions. The 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 protective functions. Furthermore, numerous new research studies suggest that iRhom2 is an attractive emerging target for a broad range of therapeutic areas, including immunology, inflammation, oncology, infectious and metabolic diseases.

About SciRhom GmbH

SciRhom GmbH, based in IZB Martinsried, Germany, is a biotech company that translates science into the preclinical and early clinical development of novel biopharmaceuticals for the treatment of life-threatening autoimmune diseases. Based on longstanding academic research conducted at the Hospital for Special Surgery (HSS) and a well-established network of experts, SciRhom was founded in 2016 through a collaboration between academic and industry scientists with profound experience in antibody development. Since then, the company has developed first-in-class anti-iRhom2 antibodies and nominated a candidate for clinical studies. Four comprehensive patent families cover the anti-iRhom2 antibodies and iRhom2-target epitopes, securing exclusivity and protection against me-too drugs. To date, SciRhom has successfully acquired seed funding from the High-Tech Gruenderfonds (HTGF), Hospital for Special Surgery, and other institutional and private investors.

Press Release

Munich, Germany, November 15, 2023



For further information, please visit www.SciRhom.com

Contact

SciRhom GmbH

Dr. Jan Poth

Phone: + 49 (0)89 614 2412-36

Email: info@SciRhom.com

www.SciRhom.com

Targeting iRhom2 for better
treatment of autoimmune diseases