

Zenas BioPharma Obtains IND Approval in China for Phase 1/2 Study of ZB001 for the Treatment of Thyroid Eye Disease

WALTHAM, Mass and SHANGHAI, China, July X, 2022 (GLOBE NEWSWIRE) — Zenas BioPharma, a global biopharmaceutical company committed to becoming a leader in the development and commercialization of immune-based therapies for patients in need around the world, announced that it has received approval of its Investigational New Drug (IND) application from the National Medical Products Administration (NMPA) of China for the initiation of a Phase 1/2 clinical study of ZB001 for the treatment of Thyroid Eye Disease (TED). The main objective of the Phase 1/2 is to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of ZB001.

TED is a debilitating vision-threatening autoimmune disease that causes inflammation and fibrosis within the orbit of the eye. With no approved therapies for TED patients in China, treatment options are limited and often involve high doses of steroids associated with serious side effects or surgical intervention. ZB001 is a differentiated humanized monoclonal antibody targeting insulin-like growth factor 1 receptor (IGF-1R) intended for the treatment of TED.

“We are proud that the IND application for ZB001 was approved by the NMPA about two months following its submission, highlighting our team’s unique ability to efficiently execute on our development programs,” said Hua Mu, MD, PhD, Chief Executive Officer at Zenas. “We are excited to work with leading clinical experts in China to accelerate the development of ZB001 to address the significant unmet clinical need in thyroid eye disease.”

Zenas BioPharma licensed the exclusive rights to develop, manufacture and commercialize ZB001 (Viridian VRDN-001) and other compounds targeting IGF-1R in non-oncology indications in the greater China area from Viridian Therapeutics, Inc. (Viridian) in October 2020. After submitting an IND for VRDN-001 to the U.S. Food and Drug Administration in October 2021, Viridian initiated a Phase 1/2 clinical trial in December 2021 to evaluate proof of concept in TED patients in North America and released encouraging interim healthy volunteer data suggesting robust activity with excellent safety and tolerability of the candidate product.

About Zenas BioPharma

Zenas BioPharma is a global biopharmaceutical company based in the USA and China committed to becoming a leader in the development and commercialization of immune-based therapies for patients in the US, China and around the world. Zenas is rapidly advancing a deep pipeline of innovative therapeutics that continues to grow through our successful business development strategy. Our experienced leadership team and network of business partners drive operational excellence to deliver potentially transformative therapies to improve the lives of those facing autoimmune and rare diseases. For more information about Zenas BioPharma, please visit www.zenasbio.com and follow us on Twitter at [@ZenasBioPharma](https://twitter.com/ZenasBioPharma) and [LinkedIn](https://www.linkedin.com/company/zenasbio).

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