

# Zenas BioPharma Submits Investigational New Drug Application in China for ZB001 for the Treatment of Thyroid Eye Disease

WALTHAM, Mass. and SHANGHAI, China, May 16, 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, today announced the submission of an investigational new drug (IND) application to the China National Medical Products Administration (NMPA) for the initiation of a Phase 1/2 clinical study of ZB001 for the treatment of Thyroid Eye Disease (TED). This study is designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of ZB001.

“The ZB001 IND submission to the NMPA marks a significant milestone for Zenas,” said Hua Mu, MD, PhD, Chief Executive Officer at Zenas. “There are currently 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 has the potential to change the treatment paradigm for TED patients in China.”

ZB001 is a differentiated humanized monoclonal antibody targeting insulin-like growth factor 1 receptor (IGF-1R) for the treatment of TED. TED is a debilitating autoimmune disease that causes inflammation and fibrosis within the orbit of the eye, which can cause double vision, pain, and potential blindness. Patients with severe disease often require multiple remedial surgeries to the orbit, eye muscles and eyelids.

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 area of China from Viridian Therapeutics, Inc. (Viridian) in October 2020. In October 2021, Viridian submitted an IND for VRDN-001 to the U.S. Food and Drug Administration and in December 2021 initiated a Phase 1/2 clinical trial to evaluate proof of concept in TED patients in North America.

## 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](http://www.zenasbio.com) and follow us on Twitter at [@ZenasBioPharma](https://twitter.com/ZenasBioPharma) and [LinkedIn](https://www.linkedin.com/company/zenasbiopharma).

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# Zenas BioPharma 在中国提交 ZB001 用于治疗甲状腺眼病的试验新药申请

马萨诸塞州沃尔瑟姆和中国上海, May 16, 2022 (GLOBE NEWSWIRE) – Zenas BioPharma (泽纳仕生物医药), 一家致力于为全球有需要患者开发和提供免疫治疗药物并成为该领域领先企业的全球性生物医药公司, 今天宣布已经向中国国家药品监督管理局 (NMPA) 提交并获得受理一项试验性新药 (IND) 申请, 以启动 ZB001 治疗甲状腺眼病 (TED) 的 1/2 期临床研究。该项研究旨在评估 ZB001 的安全性、耐受性、药代动力学和初步疗效。

Zenas 首席执行官牟骅博士表示: “向 NMPA 提交 ZB001 的 IND 申请对于 Zenas 而言是一个重要里程碑。中国目前还没有获批的 TED 患者治疗药物, 患者的治疗选择有限并且通常涉及会出现严重副作用的高剂量类固醇或手术干预。ZB001 有可能改变中国 TED 患者的治疗模式。”

ZB001 是一种具有差异化特点的人源化单克隆抗体, 靶向胰岛素样生长因子 1 受体 (IGF-1R) 以治疗 TED。TED 是一种使人衰弱的自身免疫性疾病, 会引起眼眶内的炎症和纤维化, 从而导致复视、疼痛甚至失明。重症患者通常需要接受眼眶、眼部肌肉和眼睑部位的多项治疗手术。

Zenas BioPharma 于 2020 年 10 月获得 Viridian Therapeutics, Inc. (Viridian) 的独家授权, 在大中华区开发、生产和商业化 ZB001 以及其它针对 IGF-1R 的药物用于治疗非肿瘤适应症。2021 年 10 月, Viridian 向美国食品药品监督管理局提交了 ZB001 (Viridian 称之为 VRDN-001) 的 IND 申请, 并于 2021 年 12 月启动了 1/2 期临床试验, 在北美 TED 患者中进行概念验证 (proof of concept) 评估。

## 关于 Zenas BioPharma

Zenas BioPharma 是一家立足于美国和中国的全球性生物医药公司, 致力于成为美国、中国乃至世界各地患者免疫疗法开发和商业化的领先企业。Zenas 深厚的创新治疗药物研发管线正在快速推进, 并通过我们成功的商务拓展策略持续增长。我们经验丰富的领导团队和广泛的业务合作伙伴共同致力于推动卓越运营, 为自身免疫疾病以及罕见病患者提

供潜在的变革性疗法，从而改善患者的生活。如需有关 Zenas BioPharma 的更多信息，请访问 [www.zenasbio.com](http://www.zenasbio.com)，并通过 Twitter (@ZenasBioPharma) 和 LinkedIn 关注我们。

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