GenEditBio
Affordable Precision DNA Surgery

Press Release

GenEditBio Receives NMPA Clearance of IND Application for Its Lead *In Vivo* Genome-Editing Program GEB-101 for TGFBI-Related Corneal Dystrophies

[HONG KONG, July 2, 2026] – GenEditBio Limited ("GenEditBio"), a clinical-stage biotechnology startup focusing on genome-editing therapeutic solutions, today announced that the China National Medical Products Administration (NMPA) has cleared the company's Investigational New Drug (IND) application to initiate Phase 1/2 CLARITY trial activities for its lead *in vivo* genome-editing program GEB-101 for TGFBI-related corneal dystrophies in China. This landmark regulatory milestone follows the program's initial IND clearance by the U.S. Food and Drug Administration (FDA) in December 2025.

The multi-regional Phase 1/2 CLARITY trial will collect data on the safety, tolerability and preliminary efficacy of GEB-101 in corneal dystrophy patients with TGFBI mutation. The study has a seamless, adaptive, multicenter design. Study eyes of trial participants will receive a single corneal intrastromal injection of GEB-101. Patient enrollment is expected to commence this year after site activation in China.

"Securing NMPA clearance validates both the robustness of our preclinical safety and efficacy data for GEB-101, as well as the methodological rigor of the trial design. This lead clinical asset leverages the *in vivo* delivery of CRISPR-based genome editors as ribonucleoprotein complexes via our innovative protein delivery vehicle (PDV) technology. This modality is ready-to-act, offering high target-tissue editing efficiency, rapid post-editing degradation, and a favorable safety profile with low off-target activity," said Zongli ZHENG, PhD, Co-Founder and Chairman of GenEditBio.

"With both NMPA and FDA clearances secured, GenEditBio is well-positioned to execute a global clinical strategy for advancing GEB-101 into trial evaluation in a larger patient population. This brings us closer to delivering innovative medicines to patients suffering from debilitating corneal diseases. We greatly look forward to close collaboration with the CLARITY trial investigators and renowned academic medical institutions in China and the U.S.," said Tian ZHU, PhD, Co-Founder and CEO of GenEditBio.

About TGFBI-Related Corneal Dystrophies

TGFBI-related corneal dystrophies is a group of genetic eye disorders caused by mutations in the *TGFBI* gene, resulting in progressive abnormal protein buildup and deposits in the cornea. Symptoms include photophobia, gradual vision loss and recurrent corneal erosions with debilitating pain, impacting patients' long-term quality of life. Current treatment options include phototherapeutic keratectomy (PTK) and corneal transplantation. Both procedures, however, have known limitations such as high rates of recurrence and the risk of sight-threatening complications, underscoring the urgent need for novel therapies.

About GEB-101

GEB-101, a wholly owned program of GenEditBio, is an investigational first-in-class somatic genome-editing drug candidate designed as a one-and-done treatment for TGFBI-related corneal dystrophies. GEB-101 is based on the CRISPR-Cas genome-editing technology that targets a particular locus in the mutated TGFBI gene. GEB-101 is encapsulated in the form of ribonucleoprotein in engineered protein delivery vehicle (PDV), a proprietary *in vivo* delivery system developed by GenEditBio. GEB-101 is to

be administered by a single corneal intrastromal injection and is being investigated for safety and preliminary efficacy in an investigator-initiated trial (IIT) in China. GEB-101 has received regulatory IND clearances from China and the U.S.

About GenEditBio

Established in 2021 and headquartered in Hong Kong, China, GenEditBio is a clinical-stage gene therapy startup with a strategic goal of developing *in vivo* genome-editing therapeutic solutions (dubbed "DNA surgery") that are fundamentally safe, precise, efficacious, and affordable for genetic diseases with unmet needs. The Company's core areas of focus include novel Cas nuclease discovery and safe and efficient cargo delivery utilizing lipid nanoparticle (LNP) and engineered protein delivery vehicle (PDV). We have research laboratories and supporting offices in Hong Kong, Beijing, and Boston. GenEditBio is financially backed by top-tier life science investors, including Qiming Venture Partners, Fangyuan Capital, Center Biotherapeutics, Lumosa Therapeutics, HKSTP Venture Fund, and others. For more information, please visit www.geneditbio.com.

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