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Company Name: GNI Group Ltd.
Representative: Director, Representative Executive Officer, President and CEO
Ying Luo, PhD
(Security Code: 2160, TSE Growth)
Contact Person: Director, Executive Officer, Vice President COO and CFO
Ryosuke Matsui
(TEL. 03-6214-3600)

Announcement of Priority Review Designation by China's NMPA for F351, a Treatment for Chronic Hepatitis B–Induced Liver Fibrosis

(Note) This document has been translated from the Japanese original for reference purposes only. In the event of any discrepancy between this translated document and the Japanese original, the Japanese original shall prevail.

GNI Group Ltd. ("the Company") announces that its consolidated subsidiary, Gyre Therapeutics, Inc. (hereinafter "Gyre Therapeutics"), announced today that the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China has designated F351 for Priority Review as a treatment for liver fibrosis caused by chronic hepatitis B (CHB). F351 is a therapeutic candidate for liver fibrosis associated with CHB, which is liver damage resulting from infection with the hepatitis B virus (HBV).
This decision was made following the pre-NDA meeting disclosed on January 6, 2026 (JST), and represents an important milestone in the NDA process. Gyre Therapeutics plans to submit a formal NDA* in the near future through its subsidiary, Gyre Pharmaceuticals Co., Ltd.

Mr. Ping Zhang, Executive Chairman of Gyre Therapeutics, commented as follows:
"I am very pleased to see the decision by the Chinese CDE to grant priority review to our NDA for F351. It underscores both the urgency of the medical need to treat liver fibrosis and the potential of F351 as an innovative therapeutic option. HBV infection affects tens of millions of patients in China and a significant number of them will develop liver fibrosis and eventually cirrhosis. If approved, F351 could address the need for these patients. We thank the agency for their continued support to advance therapies for liver fibrosis patients in need of treatment and look forward to working closely with CDE to move F351 toward approval."

About Priority Review Designation by the NMPA in China
Priority review was established in China in 2017 to facilitate drug registration and accelerate the development of new drugs with clinical value under the guidance of Opinions on Encouraging Pharmaceutical Innovation via Priority

Review & Approval. According to these guidelines, the NMPA will prioritize the review of these applications and allocate additional evaluation resources, which is expected to accelerate the review process.

*An NDA utilizing conditional approval pathway (based on GNI's interpretation)

See the disclosure dated January 6, 2026: https://ssl4.eir-parts.net/doc/2160/tdnet/2737447/00.pdf

[For Reference]

Press release issued by Gyre Therapeutics, Inc.

Gyre Therapeutics Announces China's NMPA Grants Priority Review to the NDA for Hydronidone (F351) for CHB-Induced Liver Fibrosis Treatment