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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: Executive Officer, CSO
Takuya Kaneko
(TEL. 03-6214-3600)

Notice Regarding Third Quarter 2026 Financial Results and Update on the F351 NDA Review by Our Subsidiary Gyre Therapeutics

(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. (NASDAQ: GYRE, "Gyre"), has released its financial results for the third quarter of 2026, prepared in accordance with U.S. Generally Accepted Accounting Principles (U.S. GAAP), along with updates on its key business activities. The announcement also includes an update on the regulatory review of the New Drug Application (NDA) for F351, a treatment for liver fibrosis associated with chronic hepatitis B (CHB).

Ying Luo, Chief Executive Officer of Gyre, commented on the key business developments as follows:

"I am pleased with our execution in the third quarter, our first full quarter incorporating Cullgen's operations within Gyre Therapeutics. We are advancing our protein degrader pipeline toward first-in-human data and initiating new clinical programs next year. Meanwhile, after recently completing an onsite inspection by China's National Medical Products Administration, or NMPA, we continue to prepare for the China NMPA decision on F351 for CHB-induced liver fibrosis, which we anticipate launching, if approved, sometime in the first half of 2027. Together, these programs are expected to drive our next phase of growth and demonstrate the strength of our unique business model, combining U.S. innovation with capital-efficient operations in China."

Update on the F351 NDA Review

In May 2026, Gyre announced that the Center for Drug Evaluation (CDE) of the NMPA had accepted the NDA for F351 (hydronidone) for the treatment of CHB-associated liver fibrosis. The application was submitted through Gyre's consolidated subsidiary, Gyre Pharmaceuticals Co., Ltd., following the NMPA's grant of priority review status to F351 in March 2026. During the third quarter of 2026, Gyre Pharmaceuticals completed an on-site inspection conducted by the NMPA of its manufacturing plants and clinical centers.

Gyre believes that the NMPA's regulatory decision on F351 could be issued by the end of 2026 or in the first quarter of 2027.

Reference: Gyre Therapeutics, Inc. Form 8-K filed on November 5, 2026
Form 8-K for Gyre Therapeutics INC filed 11/05/2026