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**Notice Regarding Completion of the Pre-NDA Meeting on the Regulatory Strategy for F351
Following Potential Eligibility for Priority Review**

(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. (“Gyre Therapeutics”), has completed a Pre–New Drug Application (Pre-NDA) meeting with the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of the PRC in connection with the New Drug Application (NDA) for F351.

As disclosed on May 23, 2025, Gyre Therapeutics obtained favorable results from the Phase 3 clinical trial of F351. During the Pre-NDA meeting with the CDE, based on the clinical trial data, Gyre Therapeutics confirmed with the regulatory authority that submission of an NDA utilizing PRC’s conditional approval pathway would be acceptable, and that F351 may potentially qualify for inclusion in the Priority Review process.

F351 was designated as a Breakthrough Therapy by the CDE in 2021, and as a result, it is eligible for consideration under the Priority Review process, which is intended to shorten the regulatory review period.

Gyre Therapeutics aims to submit an NDA for F351 in the first half of 2026 and will proceed with preparations for conducting a confirmatory clinical trial intended to support the potential conversion from conditional approval to regular approval.

The Company will promptly disclose any matters that require disclosure should they arise in the future.

[For Reference]

Press release issued by Gyre Therapeutics, Inc.

[Gyre Therapeutics Announces Alignment with China's CDE on Conditional Approval Pathway and Priority Review Eligibility for Hydronidone Following Pre-NDA Meeting | Gyre Therapeutics, Inc](#)

[Contact Information for Inquiries Regarding This Matter (Gyre Therapeutics, Inc.)]

URL: <https://www.gyretx.com/contact/>