May 13, 2026

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Announcement of Acceptance of New Drug Application (NDA) for F351 for the Treatment of Chronic Hepatitis B-induced Liver Fibrosis in China

(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 Co., Ltd. (the "Company") is pleased to announce that Gyre Pharmaceuticals Co., Ltd. ("Gyre Pharmaceuticals"), the operational subsidiary of the Company's consolidated subsidiary, Gyre Therapeutics, Inc. (Nasdaq: GYRE, "Gyre"), has received a formal notice of acceptance for its New Drug Application (NDA) for F351 (generic name: Hydronidone) from the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China. F351 is being developed for the treatment of liver fibrosis resulting from chronic hepatitis B.

1. Background and Overview of the Acceptance

   Regarding F351, a primary development candidate of the Group, the NDA was submitted on March 22, 2026, through Gyre Pharmaceuticals Co., Ltd. (Beijing Continent), the Chinese subsidiary of Gyre Therapeutics, Inc. Following a review by the CDE regarding the formality of the application documents and the completeness of the content, a formal acceptance number has been issued. Accordingly, F351 has officially transitioned to the substantive review process toward regulatory approval.

2. About F351 and Priority Review Designation

   F351 is an innovative drug candidate being developed for the indication of liver fibrosis associated with chronic hepatitis B (CHB). On March 18, 2026, F351 was granted Priority Review designation by the NMPA. The Priority Review system is applied to new drugs with significant clinical value, and it is expected to facilitate a shortened review timeline compared to the standard process.

3. Social Mission and Significance of Development

F351 holds the potential to provide a new therapeutic option and hope for patients suffering from CHB-induced liver fibrosis, a condition for which no effective treatments have yet been established. In China and across Asia, CHB is a profoundly serious national health concern. If left untreated, the resulting liver fibrosis carries the risk of progressing to life-threatening conditions such as cirrhosis and hepatocellular carcinoma (liver cancer). However, there is currently no approved drug that directly inhibits or improves the progression of such fibrosis. The Group recognizes that delivering F351 to clinical settings as expeditiously as possible is a major social responsibility as a global bio-pharma company, aimed at liberating patients and their families from the anxieties of future disease progression.

4. Future Outlook

The impact of this milestone on the consolidated financial results for the fiscal year ending December 31, 2026, is currently under review, as it will depend on the progress of the aforementioned regulatory deliberations, as well as the timing of approval and subsequent commercial launch. Nevertheless, the Company believes this development will significantly enhance both long-term corporate value and social value. We will promptly announce any further matters that require disclosure based on the progress of the review.

[For Reference] Press Release issued by Gyre Therapeutics, Inc. dated May 12, 2026

Gyre Therapeutics Announces NMPA Acceptance of New Drug Application for F351 (hydronidone) for CHB-Induced Liver Fibrosis Treatment | Gyre Therapeutics, Inc