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

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SAN DIEGO, March 17, 2026 (GLOBE NEWSWIRE) -- Gyre Therapeutics, Inc. (Gyre or Gyre Therapeutics) (Nasdaq: GYRE), a San Diego-based innovative commercial stage biopharmaceutical company with operations in the United States and China, today announced that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) has granted priority review status to the New Drug Application (NDA) for Hydronidone (F351) as a treatment for chronic hepatitis B (CHB)-induced liver fibrosis, which is liver damage resulting from the infection of the hepatitis B virus (HBV). This decision by CDE was made following the pre-NDA communication meeting previously announced on January 5, 2026 and is a major milestone in the NDA process. Gyre, through its majority-owned subsidiary, Gyre Pharmaceuticals Co., Ltd. (Gyre Pharmaceuticals), plans to submit a formal NDA in the near future.

Mr. Ping Zhang, Executive Chairman of Gyre, stated, "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.

About Hydronidone (F351)

Hydronidone, also known as F351, is a novel, orally administered anti-fibrotic agent designed to target key liver fibrosis pathways. It attenuates hepatic stellate cell activation and fibrogenesis, at least in part, by suppressing TGF-β1-induced signal transduction, including reduced p38γ phosphorylation and upregulated Smad7 expression. This upregulation of Smad7 subsequently leads to downregulation of TGF-βRI and inhibition of Smad2/3 activation, thereby disrupting canonical TGF-β/Smad signaling and reducing fibrotic gene expression in HSCs.

The drug has completed Phase 3 clinical evaluation in China for CHB-associated liver fibrosis, including early (compensated) cirrhosis, and is being evaluated for its potential applicability across additional fibrotic diseases in region-specific development programs.

About CHB-Induced Liver Fibrosis

CHB-induced liver fibrosis is the accumulation of scar tissue (collagen) in the liver caused by persistent inflammation from hepatitis B virus. According to the World Health Organization, approximately 254 million people worldwide were living with CHB infection in 2022, with 1.2 million new infections each year, and 1.3 million deaths globally. CHB is the leading aetiology of liver fibrosis and liver cancer globally, with up to 36% of all CHB patients globally developing cirrhosis. CHB prevalence varies across geographies with China and the United States estimated to have among the highest number of CHB cases.

About Gyre Pharmaceuticals

Gyre Pharmaceuticals is a commercial-stage biopharmaceutical company committed to the research, development, manufacturing and commercialization of innovative drugs for organ fibrosis. Its flagship product, ETUARY® (pirfenidone capsule), was the first approved treatment for IPF in the PRC in 2011 and has maintained a prominent market share (2024 net sales of $105.8 million). In addition, Gyre Pharmaceuticals' pipeline includes Hydronidone, a structural analogue of pirfenidone, which demonstrated statistically significant fibrosis regression after 52 weeks of treatment in a pivotal Phase 3 clinical trial in CHB-associated liver fibrosis in the PRC. Hydronidone received Breakthrough Therapy designation by the NMPA Center for Drug Evaluation in March 2021. Gyre Pharmaceuticals is also developing treatments for PD, RILI with or without immune-related pneumonitis, COPD, PAH

and ALF/ACLF. As of the third quarter of 2025, Gyre Therapeutics owns a 69.7% equity interest in Gyre Pharmaceuticals.

About Gyre Therapeutics

Gyre Therapeutics is a biopharmaceutical company headquartered in San Diego, CA, primarily focused on the development and commercialization of Hydronidone for liver fibrosis including MASH in the U.S. Gyre's strategy builds on its experience in mechanistic studies using MASH rodent models and clinical studies in CHB-induced liver fibrosis. In the PRC, Gyre is advancing a broad pipeline through its indirect controlling interest in Gyre Pharmaceuticals, including therapeutic expansions of ETUARY, and development programs for F573, F528, and F230. On March 2, 2026 Gyre announced its agreement to acquire Cullgen Inc., a privately-held, clinical-stage biopharmaceutical company focused on the discovery and development of targeted protein degraders and degrader antibody conjugate therapies.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this press release, are forward-looking statements, including statements concerning: the expectations regarding Gyre's research and development efforts and the timing of expected clinical readouts and regulatory filings, including the anticipated timing of the filing of Gyre's NDA with the NMPA for the conditional approval of Hydronidone for the treatment of CHB-associated liver fibrosis and early cirrhosis and the initiation of the confirmatory Phase 3c clinical trial of Hydronidone to support full approval in China. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our plans, estimates, and expectations, as of the date of this press release. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this press release. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: Gyre's ability to execute on its clinical development strategies; positive results from a clinical trial may not necessarily be predictive of the results of future or ongoing clinical trials; the timing or likelihood of regulatory filings and approvals; competition from competing products; the impact of general economic, health, industrial or political conditions in the United States or internationally; the sufficiency of Gyre's capital resources and its ability to raise additional capital; supply chain and distribution delays and challenges. Additional risks and factors are identified under "Risk Factors" in Gyre's Annual Report on Form 10-K for the year ended December 31, 2025 filed on March 13, 2026 and in other filings with the Securities and Exchange Commission.

Gyre expressly disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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