Gyre Therapeutics Announces Alignment with China's CDE on Conditional Approval Pathway and Priority Review Eligibility for Hydronidone Following Pre-NDA Meeting

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- Gyre Pharmaceuticals completed a Pre-NDA meeting with China's CDE, which agreed that the existing Phase 3 clinical data support a conditional approval filing for Hydronidone and priority review eligibility, subject to formal approval.
- Gyre Pharmaceuticals plans to submit an NDA in the first half of 2026 and conduct a confirmatory clinical trial to support full approval in China.

SAN DIEGO, Jan. 05, 2026 (GLOBE NEWSWIRE) -- Gyre Therapeutics, Inc. (Gyre or the Company) (Nasdaq: GYRE), an innovative, commercial-stage biopharmaceutical company dedicated to advancing fibrosis-first therapies across organ systems affected by chronic disease, today announced that its majority-owned subsidiary in China, Gyre Pharmaceuticals Co., Ltd. (Gyre Pharmaceuticals), completed a Pre–New Drug Application (Pre-NDA) communication meeting with the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) regarding Hydronidone, the Company's first-in-class anti-fibrotic therapy.

During the meeting, Gyre Pharmaceuticals and the CDE reached consensus that existing Phase 3 clinical data for Hydronidone, based on histologic improvement in liver fibrosis as measured by the Ishak fibrosis score, are generally supportive of submission of a conditional approval NDA for the treatment of chronic hepatitis B (CHB)-associated liver fibrosis, including early (compensated) cirrhosis. The CDE further indicated that Hydronidone meets the criteria for inclusion in China's Priority Review and Approval Program for Innovative Drugs, subject to formal filing, acceptance and regulatory review.

The NMPA previously granted Hydronidone Breakthrough Therapy Designation in March 2021, recognizing its potential to address a serious condition with significant unmet medical need. This designation supports eligibility for priority review, which is intended to facilitate an accelerated regulatory review process for innovative therapies.

As previously disclosed on May 22, 2025, Gyre reported topline results from its Phase 3 trial in CHB-associated liver fibrosis demonstrating that Hydronidone met its primary endpoint, with 52.85% of treated patients achieving ≥1-stage fibrosis regression at Week 52, compared with 29.84% in the placebo group (p=0.0002), based on centralized, blinded Ishak histologic assessment. The trial also achieved a key secondary endpoint evaluating improvement in liver inflammation without fibrosis progression and demonstrated a favorable safety profile consistent with prior clinical experience.

As part of the agreed regulatory pathway, the Company plans to conduct an additional confirmatory clinical trial (referred to as a Phase 3c trial in China) designed to evaluate liver-related clinical outcomes to support potential conversion from conditional approval to regular approval.

The Company currently expects to submit an NDA for conditional approval of Hydronidone in the first half of 2026, subject to final data readiness and applicable regulatory procedures.

"Hydronidone addresses a significant unmet medical need in patients with CHB-associated liver fibrosis, for whom there are currently no approved anti-fibrotic therapies," said Ping Zhang, Interim Chief Executive Officer of Gyre. "We are encouraged by the positive and constructive Pre-NDA dialogue with the CDE and the alignment achieved on a clear regulatory pathway. This milestone reflects the strength of our Phase 3 clinical data and supports our plans to advance Hydronidone toward conditional approval in China."

About Hydronidone

Hydronidone 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 the CHB Fibrosis Market in China

CHB-associated liver fibrosis represents a significant unmet medical need in China. According to China's national hepatitis B serological survey and internal epidemiological modeling, it is estimated that 60–70 million people in China are infected with hepatitis B virus, of whom approximately 14.7 million are diagnosed. Among these patients, an estimated 2.6 million have diagnosed, compensated, clinically significant liver fibrosis (F2–F4), excluding decompensated cirrhosis, and may be eligible for anti-fibrotic intervention.

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.

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, 2024 filed on March 17, 2025 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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