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

May 12, 2026

SAN DIEGO, May 12, 2026 (GLOBE NEWSWIRE) -- Gyre Therapeutics, Inc. (“Gyre”, “Gyre Therapeutics” or the “Company”) (Nasdaq: GYRE), an 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 accepted its New Drug Application (NDA) for F351 (hydronidone) 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). The acceptance comes after the NMPA previously granted priority review status for F351 in March after Gyre submitted the NDA through its majority-owned subsidiary Gyre Pharmaceuticals Co., Ltd. (Gyre Pharmaceuticals). This marks the second major product for which Gyre has submitted an NDA to the NMPA, and is a significant milestone for the Company in the commercialization of a new medication for the treatment of CHB-induced liver fibrosis.

Dr. Ying Luo, President and Chief Executive Officer of Gyre, commented, “This is another significant achievement for Gyre. This NDA is our third submission accepted for review by the NMPA, and the first one for our F351 program. Our interactions with the CDE have been very positive to date, reinforcing the agency’s support for addressing the medical need to treat liver fibrosis and the potential of F351 as an innovative therapeutic option. If approved, F351 could address the tens of millions of patients in China with HBV infection, many of whom will develop liver fibrosis and potentially cirrhosis. We look forward to working closely with CDE to progress F351 towards commercial 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 F351 (hydronidone)

F351 is Gyre’s lead development candidate for the treatment of liver fibrosis that is being developed for two different indications. It is a structurally modified derivative of pirfenidone designed to optimize metabolic properties while targeting the TGF-β1 signaling pathway, a key mediator of fibrogenesis. Gyre is developing F351 for two primary indications: Chronic hepatitis B (CHB)-associated liver fibrosis in the People’s Republic of China (PRC) and MASH-associated liver fibrosis initially in the United States.

In the United States, Gyre has completed a Phase 1 clinical trial in healthy volunteers evaluating F351’s safety, tolerability, and PK. Gyre plans to file an Investigational New Drug (IND) application in the U.S. by the end of 2026, and, if the IND becomes effective, to initiate a Phase 2 clinical trial.

About CHB-Induced Liver Fibrosis

Liver fibrosis is a condition where healthy tissues in the liver become scarred in response to chronic inflammation. If left untreated, it can progress to cirrhosis—the final, severe stage where extensive scarring permanently distorts the liver’s architecture and significantly impairs its vital functions. Viral hepatitis is estimated to cause up to 50% of fibrosis and 65% of cirrhosis worldwide. Without intervention, liver fibrosis and cirrhosis typically progress from manageable organ damage to systemic, life-threatening liver failure and hepatocellular carcinoma (HCC). No non-viral directed therapy has been shown to reduce fibrosis in viral induced hepatitis.

About Gyre Pharmaceuticals

Gyre Pharmaceuticals Co., Ltd., a subsidiary of Gyre Therapeutics, Inc., 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 over the past several years. In addition, Gyre Pharmaceuticals’ pipeline includes F351 (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. F351 received Breakthrough Therapy designation by the

CDE of the NMPA 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 March 31, 2026, Gyre Therapeutics owns a 69.7% equity interest in Gyre Pharmaceuticals.

About Gyre Therapeutics

Gyre Therapeutics is a commercial-stage biopharmaceutical company headquartered in San Diego, CA focused on the development and commercialization of small-molecule therapeutics with its most advanced programs addressing organ fibrosis and inflammatory diseases.

Gyre's wholly-owned subsidiary, Cullgen Inc., is a clinical-stage biopharmaceutical company focused on the discovery and development of targeted protein degrader and degrader-antibody conjugate (DAC) therapies for critical conditions including cancer and inflammatory diseases. Cullgen has created a portfolio of highly selective targeted protein degrader and DAC product candidates designed to potently and efficiently eliminate therapeutically relevant proteins in patients.

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 development and commercial potential and potential benefits of F351; the timing and progression of commercial approval of F351; and the timing of Gyre's IND application in the U.S., and, if the IND becomes effective, initiation of a Phase 2 clinical trial for F351. 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: unexpected costs, charges or expenses resulting from the acquisition; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the acquisition; the risk that the combined company may not be able to successfully integrate the businesses and realize the expected benefits of the acquisition in a timely manner or at all; the uncertainties associated with Gyre's and Cullgen's product candidates, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; risks related to the inability of the combined entity to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs; uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; risks associated with the possible failure to realize certain anticipated benefits of the acquisition, including with respect to future financial and operating results. 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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