Gyre Therapeutics Announces Last Patient Completed Pivotal Phase 3 Trial Evaluating F351 for CHB-Associated Liver Fibrosis

October 22, 2024

SAN DIEGO, Oct. 22, 2024 (GLOBE NEWSWIRE) -- Gyre Therapeutics, Inc. (“Gyre”) (Nasdaq: GYRE), a self-sustainable, commercial-stage biotechnology company with clinical development programs focusing on a variety of chronic organ diseases, today announced that the last patient in Gyre Pharmaceuticals’ pivotal Phase 3 trial in the People’s Republic of China (“PRC”) evaluating F351 (hydronidone) for Chronic Hepatitis B (“CHB”)-associated liver fibrosis has completed the 52-week study. Gyre Pharmaceuticals expects to report topline data from this trial by the first quarter of 2025.

“The final patient completing our pivotal F351 Phase 3 trial marks an important milestone for Gyre and our development pipeline. We are grateful to the patients, researchers, trial investigators, and various teams who supported this trial and look forward to sharing data in the first quarter of 2025,” said Han Ying, Ph.D., CEO of Gyre Therapeutics. “Furthermore, we are excited to potentially use these results to spur initiation of our Phase 2 clinical trial in the United States evaluating F351 for Metabolic Dysfunction-Associated Steatohepatitis (“MASH”)-associated fibrosis in 2025.”

The randomized, double-blind, placebo-controlled, multicenter Phase 3 trial (NCT05115942) enrolled 248 patients across 39 clinical research hospitals in the PRC. Patients were randomized 1:1 to receive either F351 or placebo in addition to entecavir antiviral basic therapy for CHB. The primary endpoint is a decrease in liver fibrosis (as measured by the Ishak Scoring System) by at least one stage after 52 weeks of treatment relative to baseline. China’s National Medical Products Administration (“NMPA”) designated F351 as a “Breakthrough Therapy” in 2021.

About Hydronidone (F351)

F351 is a structural analogue of the approved anti-fibrotic drug Pirfenidone (approved in the PRC for the treatment of idiopathic pulmonary fibrosis) and has been shown to inhibit in vitro both p38γ kinase activity and TGF-β1-induced excessive collagen synthesis in hepatic stellate cells (“HSCs”), which are recognized as critical event in the development and progression of fibrosis in the liver. This is further supported by its anti-proliferative effects on the HSCs in the liver. In vitro anti-fibrotic effects of F351 were also confirmed in several established in vivo models of liver fibrosis, such as CCl_4-induced liver fibrosis mouse model, DMN-induced liver fibrosis rat model, and HSA-induced liver rat model, as well as mouse model of MASH fibrosis (CCl_4+Western High Fat Diet).

About Gyre Therapeutics

Gyre Therapeutics is a biopharmaceutical company headquartered in San Diego, CA, with a primary focus on the development and commercialization of F351 (Hydronidone) for the treatment of MASH-associated fibrosis in the U.S. Gyre’s development strategy for F351 in MASH is based on the Company’s experience in MASH rodent model mechanistic studies and CHB-induced liver fibrosis clinical studies. Gyre is also advancing a diverse pipeline in the PRC through its indirect controlling interest in Gyre Pharmaceuticals, including ETUARY therapeutic expansions, F573, F528, and F230.

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 (2023 net sales of $112.1 million). In addition, Gyre Pharmaceuticals is evaluating F351 in a Phase 3 clinical trial in CHB-associated liver fibrosis in the PRC, which is expected to readout topline data by the first quarter of 2025. F351 received Breakthrough Therapy designation by the National Medical Products Administration’s Center for Drug Evaluation in March 2021. Gyre Pharmaceuticals is also developing treatments for COPD, PAH and ALF/ACLF. In October 2023, Gyre Therapeutics acquired an indirect majority interest in Gyre Pharmaceuticals (also known as Beijing Continent Pharmaceuticals Co., Ltd.).

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, timing of expected clinical readouts, including timing of topline data from Gyre Pharmaceuticals’ Phase 3 clinical trial evaluating F351 for the treatment of CHB-associated liver fibrosis in the PRC, and the initiation of Gyre’s Phase 2 trial in the U.S. 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: 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. Additional risks and factors are identified under “Risk Factors” in Gyre’s Annual Report on Form 10-K for the year ended December 31, 2023 filed on March 27, 2024 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.

For Investors:
Stephen Jasper
stephen@gilmartinir.com