Gyre Pharmaceuticals Receives IND Approval from China's NMPA to Evaluate F230 for the Treatment of Pulmonary Arterial Hypertension

May 30, 2024

SAN DIEGO, May 30, 2024 (GLOBE NEWSWIRE) -- Gyre Therapeutics ("Gyre") (Nasdaq: GYRE), a clinical-stage, self-sustainable biotechnology company developing anti-fibrotic therapeutics for a variety of chronic organ diseases, today announced that the Center for Drug Evaluation ("CDE") of China's National Medical Products Administration ("NMPA") has approved Gyre Pharmaceuticals' (Gyre's indirectly controlled subsidiary) Investigational New Drug ("IND") application for F230 tablets, a selective endothelin receptor antagonist, for the treatment of pulmonary arterial hypertension ("PAH"). F230 was originally licensed from Eisai through Gyre's indirect majority stockholder, GNI Group Ltd.

"PAH is a rare disease and a progressive, life-threatening disorder that represents a significant unmet need with no known cure," said Han Ying, Ph.D., Chief Executive Officer of Gyre. "Through Gyre Pharmaceuticals, we are committed to advancing F230 through clinical development with the ultimate goal of improving patient outcomes and enhancing the quality of life for those affected by this devastating condition."

In preclinical animal studies, F230 resulted in significant decreases of, or exhibited a decrease trend based on different dose groups in, mean pulmonary arterial pressure, right ventricular systolic pressure, right ventricular/left ventricular plus septum and pulmonary artery wall thickness. Even at the minimum effective dosage, the differences of those indexes between the treatment group and the PAH model group were statistically significant. In addition to PAH, Gyre is also exploring other disease indications for F230.

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 NASH-associated fibrosis in the U.S. Gyre's development strategy for F351 in NASH is based on the company's experience in NASH 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.

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, including the clinical development of F230 for the treatment of PAH and other disease indications, and statements regarding the therapeutic potential and utility, efficacy and clinical benefits of F230. 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.

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