Gyre Therapeutics Announces NMPA Approval for Clinical Trial Evaluating Pirfenidone Capsules in Oncology-Related Pulmonary Complications

March 31, 2025

SAN DIEGO, March 31, 2025 (GLOBE NEWSWIRE) -- Gyre Therapeutics (“Gyre”) (Nasdaq: GYRE), an innovative, commercial-stage biotechnology company focused on organ fibrosis, today announced that the National Medical Products Administration (NMPA) of the People’s Republic of China (“PRC”) has approved its clinical trial application for a potential new indication for pirfenidone in oncology-related pulmonary complications. The trial will evaluate pirfenidone capsules for the treatment of radiation-induced lung injury (RILI), with or without immune-related pneumonitis (CIP).

This regulatory milestone marks the expansion of pirfenidone beyond its established role in idiopathic pulmonary fibrosis (IPF) into the oncology supportive care space, offering a novel lung-protective strategy for cancer patients undergoing radiation therapy or immunotherapy.

In accordance with the NMPA approval, Gyre intends to pursue an adaptive Phase 2/3 clinical trial design, combining dose exploration with efficacy confirmation, to efficiently evaluate pirfenidone's potential in this new indication.

Radiation-Induced Lung Injury (RILI): Radiation therapy is a cornerstone of lung cancer treatment. However, 5%–25% of patients experience lung damage due to radiation exposure, limiting the ability to escalate doses and thereby compromising treatment efficacy.

Checkpoint Inhibitor Pneumonitis (CIP): Immune checkpoint inhibitors (ICIs) have revolutionized cancer treatment, but 13%–19% of patients develop CIP. This condition accounts for approximately 35% of immune-related adverse event (irAE) deaths and often necessitates treatment discontinuation.

Currently, no targeted therapies exist for lung injuries caused by radiation or immunotherapy. Distinguishing between RILI and CIP is challenging, particularly when both occur concurrently. Corticosteroids remain the standard of care despite significant long-term side effects. By targeting and inhibiting fibrotic pathways, pirfenidone may address the root cause of lung injury progression, offering a new treatment option for patients receiving radiation or immunotherapy.

Gyre anticipates initiating the trial in the second half of 2025 at leading academic and oncology centers across the PRC.

About Pirfenidone
Pirfenidone is an orally administered small molecule approved for the treatment of IPF. It works by inhibiting TGF-β signaling and fibroblast proliferation. The drug has demonstrated clinical benefit in slowing lung function decline in IPF and is now being evaluated for oncology-related pulmonary complications. Gyre has held first-in-class status for pirfenidone in the PRC since its original approval in 2011, underscoring its pioneering role in treating fibrotic lung diseases.

About Gyre Therapeutics
Gyre Therapeutics is a biopharmaceutical company headquartered in San Diego, CA, primarily focused on the development and commercialization of F351 (Hydronidone) for MASH-associated fibrosis 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 timing of expected clinical trials, including timing of a clinical trial initiation in the second half of 2025. 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, 2024 filed on March 17, 2025 and in other filings the Company may make 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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