Gyre Therapeutics Announces Completion of Patient Enrollment in Phase 3 Clinical Trial of Pirfenidone Capsules for the Treatment of Pneumoconiosis

October 15, 2025

SAN DIEGO, Oct. 15, 2025 (GLOBE NEWSWIRE) -- Gyre Therapeutics (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 indirect, majority-owned subsidiary, Gyre Pharmaceuticals Co., Ltd. (Gyre Pharmaceuticals), has completed patient enrollment in the 52-week Phase 3 clinical trial of its Class 1 drug, Pirfenidone capsules, for the treatment of pneumoconiosis.

A total of 272 patients have been enrolled in this multicenter, randomized, double-blind, placebo-controlled trial being conducted at 18 clinical research centers across China. The trial is designed to evaluate the efficacy and safety of 52 weeks of Pirfenidone capsule treatment in patients with pneumoconiosis, a chronic occupational lung disease characterized by progressive pulmonary fibrosis.

Unmet Medical Need in Pneumoconiosis

Pneumoconiosis remains the most common and severe occupational disease in China, with more than 450,000 surviving patients and thousands of new cases reported each year. It results from long-term inhalation of mineral dusts such as silica or coal, which triggers persistent inflammation and progressive fibrosis of the lung tissue. Over time, this excessive scar formation causes diffuse fibrosis and irreversible loss of lung function. Despite its prevalence and severity, there is currently no approved therapy in China that specifically targets the fibrotic mechanisms underlying pneumoconiosis.

Based on recent expert consensus, China's pneumoconiosis treatment landscape represents a significant unmet medical need, underscoring the importance of developing therapies specifically designed to slow or halt the progression of fibrosis and improve long-term outcomes for affected patients.

About the 52-Week Phase 3 Trial

The ongoing trial compares Pirfenidone 1,800 mg/day (600 mg tid) with placebo over a 52-week double-blind treatment period.

- **Primary Endpoint:** Change from baseline in forced vital capacity (FVC) % predicted at Week 52.
- **Key Secondary Endpoints:** Changes in diffusing capacity of the lungs for carbon monoxide (DLCO), 6-minute walk distance, St. George's Respiratory Questionnaire (SGRQ) score, and Modified Medical Research Council (mMRC) dyspnea scale, as well as rates of acute exacerbations, hospitalizations, and deaths.
- **Safety Monitoring:** Follows Gyre's Development Safety Update Report (DSUR Dec 2023–Dec 2024). Most adverse events reported to date are mild to moderate, with no unexpected safety signals.
- **Interim Analysis:** None planned.

About Pirfenidone (ETUARY®)

Pirfenidone is an oral antifibrotic small molecule that received its original approval in China in 2011 by Gyre Pharmaceuticals for the treatment of idiopathic pulmonary fibrosis (IPF). It works by inhibiting TGF-β signaling and fibroblast proliferation. Gyre continues to advance Pirfenidone beyond IPF through multiple clinical programs, including the Phase 3 pneumoconiosis trial and the recently approved Phase 2/3 trial for oncology-related pulmonary complications such as radiation-induced lung injury (RILI) and checkpoint inhibitor pneumonitis (CIP).

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 United States. Gyre's strategy builds on its experience in mechanistic studies using MASH rodent models and clinical studies in CHB-induced liver fibrosis. In the People's Republic of China, 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, including Gyre’s advancement of its Phase 3 trial in China for Pirfenidone capsules for the treatment of pneumoconiosis and the initiation of Gyre’s Phase 2/3 trial in China for Pirfenidone capsules for the treatment of RILI and CIP; and trial design of Gyre’s Phase 3 trial in China for Pirfenidone capsules for the treatment of pneumoconiosis. 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 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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