Gyre Therapeutics Announces China's NMPA Approval of Avatrombopag Maleate Tablets for the Treatment of CLD-Associated Thrombocytopenia

July 2, 2024

SAN DIEGO, July 02, 2024 (GLOBE NEWSWIRE) -- Gyre Therapeutics ("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 China's National Medical Products Administration ("NMPA") has approved Gyre Pharmaceuticals' (Gyre's indirectly controlled subsidiary) avatrombopag maleate tablets for the treatment of thrombocytopenia ("TP") associated with chronic liver disease ("CLD") in adult patients undergoing elective diagnostics procedures or therapy. TP is the most common hematologic complication in patients with CLD and can be life threatening in severe cases.

"The approval of avatrombopag maleate tablets by the NMPA represents an important milestone for Gyre as we expand our rare disease product lines and build our presence in developing treatments for patients with CLD," said Han Ying, Ph.D., CEO of Gyre Therapeutics. "We are eager to launch avatrombopag in China and provide a treatment for patients suffering from this devastating disease."

Gyre Pharmaceuticals acquired avatrombopag under a transfer agreement with Nanjing Healthnice Pharmaceutical Technology Co., Ltd. ("Nanjing Healthnice") in June 2021. Avatrombopag is an oral thrombopoietin receptor agonist ("TPO-RA"). Avatrombopag was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of adults with CLD-associated TP in May 2018, and its indication was subsequently expanded to include the treatment of immune thrombocytopenia in June 2019.

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: expectations regarding Gyre's research and development efforts, including the expansion of its rare disease pipeline; expectations regarding avatrombopag maleate tablets, including its therapeutic effectiveness and potential marketing opportunities; expectations regarding future product sales; expectations and Gyre's financial position and cash resources. 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; competition from competing products; the impact of general economic, health, industrial or political conditions in the United States or internationally; and 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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