Galecto Resumes Recruitment in Phase 2b Global GALACTIC-1 Trial of GB0139 for Idiopathic Pulmonary Fibrosis

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BOSTON, July 13, 2021 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a publicly listed biotechnology company focused on the development of novel treatments for fibrosis and cancer, today announced that it has resumed recruitment in its Phase 2b GALACTIC-1 trial of GB0139 for the treatment of Idiopathic Pulmonary Fibrosis (IPF) under a revised protocol that was submitted to the U.S. Food and Drug Administration and other regulatory bodies, including those in Australia, Germany, Spain and the United Kingdom. Following the recommendation from an independent Data Safety Monitoring Board in March 2021 to modify the GALACTIC-1 trial protocol, 38 patients continued treatment in this Phase 2b trial. Under the revised protocol, Galecto is now recruiting additional patients who are not taking nintedanib or pirfenidone at screening, who will be randomized 2:1 to receive either GB0139 3 mg or placebo.

GALACTIC-1 is a 52-week randomized, double-blind, multicenter, parallel, placebo-controlled Phase 2b trial being conducted across more than 100 centers globally, investigating the safety and efficacy of Galecto's lead inhaled compound, GB0139, in up to 210 patients with IPF. The revised trial design retains the same statistical powering to assess the primary endpoint of forced vital capacity (FVC) decline over 52 weeks. Galecto anticipates that topline data from the GALACTIC-1 trial will be available by mid-2023.

"We are pleased to continue our Phase 2b GALACTIC-1 trial of GB0139 in IPF patients. We believe the 3 mg dose of GB0139, as a single agent, has the potential to be an effective and potentially life-changing treatment. In our previous study of GB0139 in IPF patients, we showed that the 3 mg dose is well-tolerated and easy to administer for the patients. We observed target engagement at that dose level, with a decrease in lung macrophage Galectin-3 levels, as well as reduction in a number of fibrosis biomarkers, including YKL-40, PDGF, and PAI-1. Additionally, we recently announced the results of GB0139 in COVID-19 patients with compromised lung function, which confirmed that the compound was well-tolerated and showed target engagement and highly relevant biological effects," said Dr. Hans Schambye, CEO of Galecto. "Around 50% of IPF patients in Europe and the US do not receive treatment with either pirfenidone or nintedanib, representing a significant unmet medical need. We are confident in the safety of the 3 mg GB0139 dose based on our previous clinical results and the blinded data in the GALACTIC-1 trial. We are looking forward to continuing to investigate this exciting drug candidate."

GB0139
GB0139 is the world's first small molecule galectin-3 inhibitor studied in man. The compound is not taken up via the oral route and is being developed as an inhaled therapeutic in Idiopathic Pulmonary Fibrosis (https://clinicaltrials.gov/ct2/show/NCT03832946). Early phase studies have shown that inhalation of GB0139 in healthy volunteers and in IPF patients is well tolerated, and the phase 2a IPF trial showed significant effects on several biomarkers linked to worse outcomes in IPF.

About Galecto
Galecto is a clinical stage biotechnology company incorporated in the U.S. that is developing small molecule-based galectin inhibitors and the collagen cross-linking enzyme, LOXL2, inhibitors. Galecto has multiple clinical programs in fibrosis and cancer focused on galectin-3 and LOXL2, including an inhaled galectin-3 modulator (GB0139) currently in a phase 2b trial for the potential treatment of idiopathic pulmonary fibrosis. The company's pipeline also includes an orally active galectin-3 inhibitor (GB1211) that is expected to be part of (i) a phase 2 trial for the potential treatment of NSCLC in combination with an anti-PD1 product and (ii) a phase 1b/2 trial in liver cirrhosis, as well as an orally active LOXL2 inhibitor (GB2064) that is expected to part of a phase 2 trial for the potential treatment of myelofibrosis. It is anticipated that enrollment for all of these trials will be initiated in 2021.

Galecto intends to use its website as a means of disclosing material non-public information. For regular updates about Galecto, visit www.galecto.com.

Forward-Looking Statements
Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the GALACTIC-1 trial, including plans for resuming enrollment of patients, the timing of completing enrollment and releasing topline data, as well as GB0139's potential (including the safety and effectiveness of the 3 mg dose). The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. For such statements, Galecto claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Galecto's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include risks and uncertainties related to the development of Galecto's product candidates, their therapeutic potential and outcomes related to our clinical trials, our ability to continue to enroll patients and complete the GALACTIC-1 trial with fewer dosage groups, the risk that FDA or other regulatory agency imposes a clinical hold on the GALACTIC-1 trial, having adequate funds and their use, and those additional risks and uncertainties disclosed in Galecto's filings with the Securities and Exchange Commission. These forward-looking statements represent Galecto's judgment as of the time of this release. Galecto disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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