Galecto Completes Enrollment in Global Phase 2b GALACTIC-1 Trial of GB0139 for the Treatment of IPF

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GB0139 is Galecto's proprietary inhaled once-daily small molecule galectin-3 inhibitor

GALACTIC-1 trial on track to deliver top-line results in mid-2023

BOSTON, April 26, 2022 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a clinical stage biotechnology company focused on the development of novel treatments for fibrosis and cancer, today announced it has completed enrollment of patients in its Phase 2b GALACTIC-1 trial of GB0139 for idiopathic pulmonary fibrosis (IPF).

IPF is a life-threatening, rapidly progressing and irreversible disease causing scarring of the lungs and significantly impairing lung function. IPF affects approximately 100,000 people in the United States and is associated with significant morbidity and mortality, imposing substantial challenges for healthcare systems worldwide. The current standard of care treatment options for IPF have only been shown to have a modest impact on slowing the progression of the disease and have been associated with significant side effects, leading to poor therapeutic adherence.

"We are very excited to complete enrollment in this Phase 2b trial in IPF and are encouraged by the support of the clinical investigators and patients participating in the trial. Limited treatment options for patients with IPF make it an area of significant unmet need and patients would benefit from innovative and disease-modifying treatment options that are safe and well-tolerated," said Dr. Hans Schambye, President and Chief Executive Officer of Galecto. "Once-daily inhaled GB0139 offers the potential to play an important role in filling this unmet need with its demonstrated ability to specifically target galectin-3, one of the key regulators in the disease. We look forward to topline data from this study in mid-2023."

GALACTIC-1 is a randomized, double-blind, placebo-controlled, parallel-group, multicenter Phase 2b study being conducted across approximately 100 centers globally. The study is designed to investigate the safety and efficacy of Galecto's most advanced compound, GB0139, in 141 patients with IPF. Patients in GALACTIC-1 are randomized (2:1) to either receive GB0139 or placebo. Patients in the GB0139 group receive a 3mg dose of GB0139 once daily for 52 weeks. The primary endpoint of the trial is to assess the annual rate of decline in forced vital capacity (FVC). Reduction in the decline of FVC was accepted by the U.S. Food and Drug Administration as primary endpoint for the approval of the current standard of care treatments for IPF: nintedanib, marketed as Ofev® by Boehringer Ingelheim, and pirfenidone, marketed as Esbriet® by Roche/Genentech.

Dr. Bertil Lindmark, Chief Medical Officer of Galecto, stated: "The 52-week duration and the centralized read of the primary endpoint forced vital capacity (FVC) makes GALACTIC-1 a significant development for the treatment of IPF. If our preclinical data and clinical biomarker data translate to breaking the fall in lung function in IPF, GB0139 may become an important addition to the therapeutic arsenal, in IPF, a disease with cancer-like mortality."

About GB0139
GB0139 is an inhaled small molecule inhibitor of galectin-3 that is administered as a once-daily inhalation via a generic dry powder inhaler. GB0139 is designed to specifically target galectin-3, a main regulator of the fibrosis cascade. The overexpression of galectin-3 is ubiquitous in fibrotic tissue, including fibrotic lung tissue, and is linked to both disease severity and disease progression, as well as acute exacerbations of IPF.

In clinical trials completed to date, inhaled GB0139 was found to be generally well-tolerated, and inhibited galectin-3 in the lungs in a dose-dependent manner. GB0139 was observed to decrease a range of plasma biomarker levels, such as YKL-40 and platelet-derived growth factor (PDGF), that have been linked to mortality, disease severity and disease progression in IPF.

There are currently no approved therapeutics that specifically target galectin-3. GB0139 for the treatment of IPF has been granted Orphan Drug Designation by both U.S. and European regulatory authorities.

For more information about the GALACTIC-1 trial, please visit www.clinicaltrials.gov (NCT03832946).

About Galecto
Galecto is a clinical stage company incorporated in the U.S. that is developing small molecule-based inhibitors of galectin-3 (and the galectin family generally) and LOXL2. Galecto has multiple ongoing Phase 2 clinical programs in fibrosis and cancer, including (i) an inhaled galectin-3 modulator (GB0139) in a phase 2b trial for the treatment of idiopathic pulmonary fibrosis (IPF); (ii) an oral LOXL2 inhibitor (GB2064) in a phase 2 trial for the treatment of myelofibrosis; (iii) an oral galectin-3 inhibitor (GB1211) in a phase 1b/2a trial in liver cirrhosis and (iv) an oral galectin-3 inhibitor (GB1211) in a planned phase 2 trial for the treatment of NSCLC in combination with atezolizumab (Tecentriq®).

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 potential tolerability and efficacy of GB0139; the primary endpoint of the GALACTIC-1 trial being accepted by the FDA; that GB0139 may become an important addition to the therapeutic arsenal in the treatment of IPF, the timing of top-line results from the GALACTIC-1 trial, as well as Galecto's general focus and plans for clinical development of its product candidates and pipeline. 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 and their therapeutic potential, having adequate funds and their use, and those disclosed in Galecto's filings with the Securities and Exchange Commission (SEC), including, but not limited to, Galecto's Annual Report on Form 10-K, as filed

with the SEC on February 17, 2022. 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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