Galecto Completes Dosing in 52-Week Phase 2b GALACTIC-1 Trial of GB0139 in Idiopathic Pulmonary Fibrosis

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BOSTON, May 23, 2023 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a clinical-stage biotechnology company and world leader in galectin biology focused on the development of novel treatments for fibrosis and cancer, today announced the last dosing of the last patient in the GALACTIC-1 Phase 2b trial of its most advanced product candidate, GB0139, for the treatment of idiopathic pulmonary fibrosis (IPF).

GALACTIC-1 is a randomized, double-blind, placebo-controlled, parallel-group, multicenter trial being conducted across approximately 100 centers globally. The study is designed to investigate the safety and efficacy of GB0139 in patients with IPF. 144 patients were randomized (2:1) to receive either a 3 mg dose of GB0139 or placebo once daily for 52 weeks. The primary endpoint of the trial is to assess the annual rate of decline in forced vital capacity (FVC) in adults who are not treated with or cannot tolerate nintedanib or pirfenidone. Reduction in the decline of FVC was accepted by the U.S. Food and Drug Administration as the primary endpoint in pivotal studies of the current standard-of-care treatments for IPF: nintedanib, marketed as Ofev® by Boehringer Ingelheim, and pirfenidone, marketed as Esbriet® by Roche/Genentech.

“We are pleased to have completed dosing in the GALACTIC-1 trial, which is a component in Galecto’s quest to develop anti-fibrotic drugs,” said Dr. Hans Schambye, President and Chief Executive Officer of Galecto. “GB0139 has been shown to specifically target galectin-3, one of the key regulators in IPF. Patients with IPF need new and more tolerable treatment options and we believe GB0139 has the potential to address this significant unmet medical need, while being easy to administer as a once-daily inhaled treatment. We’ve had significant interest in the outcome of the GALACTIC-1 trial and we plan to report topline data from this study in August 2023.”

IPF is a life-threatening, rapidly progressing, and irreversible disease, which causes scarring of the lungs and significant impairment of lung function. It 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 been shown to only have a modest impact on slowing the progression of the disease and have been associated with significant side effects, leading to poor therapeutic adherence or dose reduction.

The anticipated results from the GALACTIC-1 trial will represent the third data readout from Galecto’s anti-fibrotic clinical pipeline in the last year. In November 2022, Galecto announced topline results from its Phase 1b/2a trial of GB1211, an orally available galectin-3 inhibitor, in patients with decompensated liver cirrhosis. The topline results showed statistically significant reductions in liver enzymes and other positive biomarker effects after 12 weeks of treatment. Galecto believes that this was the first study in a population of Child-Pugh Class B decompensated cirrhosis patients of non-viral etiology to show changes in a series of liver parameters that are potentially clinically meaningful. Additionally, in September 2022, Galecto announced data from an intermediate assessment from its Phase 2a trial of GB2064 for myelofibrosis that showed four out of five evaluable myelofibrosis patients experienced a ≥ 1-grade reduction in collagen fibrosis of the bone marrow. Galecto believes that this level of reduction in collagen fibrosis has not been shown in any other clinical trial and is an improvement suggesting that GB2064 has the potential to impact the progression of the disease and be disease-modifying.

About GB0139
GB0139 is an investigational 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 to inhibit 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 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 orally active LOXL2 inhibitor (GB2064) in a Phase 2a trial for the treatment of myelofibrosis; (iii) an orally active galectin-3 inhibitor (GB1211) in a recently completed Phase 1b/2a trial in liver cirrhosis; and (iv) an orally active galectin-3 inhibitor (GB1211) in combination with atezolizumab (Tecentriq®) in a separate Phase 2a trial for the treatment of non-small cell lung cancer (NSCLC).

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 Galecto’s ability to make progress across its clinical pipeline of assets; the therapeutic potential of Galecto’s product candidates, including to address significant areas of unmet need; the safety of Galecto’s product candidates; the enrollment and timing for completion of clinical trials; and Galecto’s expectation that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital requirements into the second half 2024. 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, the risk that results of earlier-stage clinical trials may not reflect the results of later-stage clinical trials, 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 March 9, 2023. 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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