Galecto Announces Outcome of Data Safety Monitoring Board Interim Review of Phase 2b GALACTIC-1 Study of GB0139 for Idiopathic Pulmonary Fibrosis: DSMB Recommends Study to Continue with Modifications

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Galecto expects to continue dosing patients in the 3 mg arm, whereas the 10 mg arm and combinations with nintedanib or pirfenidone will be discontinued at the recommendation of the DSMB

BOSTON, March 15, 2021 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a biotechnology company focused on the development of novel treatments for fibrosis and cancer, today announced that an independent Data Safety Monitoring Board (DSMB) has completed its interim review of the company's Phase 2b GALACTIC-1 study of GB0139 for the treatment of Idiopathic Pulmonary Fibrosis (IPF). On Friday, March 12, the DSMB recommended that, based upon a safety analysis of the data, the company discontinue dosing and enrolling patients in the 10 mg arm along with patients in the 3 mg arm who are receiving combination treatment with the currently approved treatments of IPF, nintedanib and pirfenidone. We expect the 3 mg and placebo arms in patients who are not on concomitant nintedanib or pirfenidone will continue enrolling patients.

GALACTIC-1 is a 52-week randomized, double-blind, multicenter, parallel, placebo-controlled Phase 2b study being conducted across more than 100 centers globally, investigating the safety and efficacy of Galecto's lead compound, GB0139, in patients with IPF. Initial unblinded data readout is anticipated in 2022.

The DSMB informed the company, based on unblinded safety and efficacy data, that there was an imbalance in the serious adverse experiences across the study groups, but not an imbalance between the groups in mortality. Galecto expects to continue recruiting patients who are not taking nintedanib or pirfenidone at screening and who would be randomized to receive GB0139 3 mg or placebo. The DSMB recommended the patients randomized to the 10mg group and all those taking nintedanib or pirfenidone should be discontinued from the study. Based on these recommendations, the Company plans to work with both the study investigators and the appropriate regulatory authorities to implement these changes promptly.

"Galecto is committed to patient safety and continuing the development of life changing treatments for patients with IPF. Around 50% of IPF patients in Europe and the US do not receive treatment with either pirfenidone or nintedanib, representing a very significant unmet medical need, as they have no available treatment options. Based on our prior phase 1b/2a study of GB0139 in IPF patients, we believe the 3 mg dose has the potential to be an effective clinical dose for these patients," said Dr. Hans Schambye, CEO of Galecto. He added "there is a very strong demand for a tolerable alternative to the approved therapies."

"We do not expect the recommended changes, which relate solely to the inhaled GB0139 in IPF, to impact any of our other planned trials. We continue to look forward to initiating three additional Phase 2 trials this year with our other clinical stage assets GB2064 (oral LOXL2 inhibitor) and GB1211 (oral Galectin-3 inhibitor). We anticipate completing enrollment in the GALACTIC-1 trial this year with initial data readout in 2022," added Dr. Schambye.

About Galecto
Galecto (NASDAQ: GLTO) is a clinical stage biotechnology company incorporated in the U.S. with advanced programs in fibrosis and cancer centered on the development of small-molecule inhibitors of galectin-3 and lysyl oxidase-like 2, or LOXL2, which play key roles in regulating fibrosis. The company's pipeline includes our lead product candidate, which is an inhaled galectin-3 modulator currently in phase 2b for the potential treatment of idiopathic pulmonary fibrosis. Our pipeline also includes two additional assets about to move into phase 2 studies.

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 continuing to enroll patients, working with investigators and regulatory authorities, the timing of completing enrollment and the initial unblinded data readout, Galecto's focus and commitment, GB0139's potential (including the effectiveness of the 3 mg dose), plans for clinical development (including the timing of their initiation) and potential to market, and Galecto's 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, their therapeutic potential and outcomes related to our clinical trials, our ability to modify the GALACTIC-1 trial protocol to the satisfaction of the FDA or other regulatory agencies, 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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