Galecto Publishes GB0139 Phase 2a Idiopathic Pulmonary Fibrosis (IPF) Results in European Respiratory Journal, Showing Marked Impact on Several IPF Biomarkers

November 30, 2020

- The ERJ Paper shows major effects on biomarkers in IPF, linked to mortality and to fall in FVC
- The inhaled GB0139 significantly reduced key plasma biomarkers from baseline vs placebo over 2 weeks
- GB0139 is being investigated in the 450 patients, 52 week GALACTIC-1 Phase 2b/3 trial in IPF

BOSTON and COPENHAGEN, Denmark, Nov. 30, 2020 (GLOBE NEWSWIRE) -- Galecto, Inc., a NASDAQ listed biotechnology company focused on the development of novel treatments for fibrosis and cancer, announced today the publication of a paper detailing full results from a phase 2a study of GB0139 in Idiopathic Pulmonary Fibrosis (IPF) in the peer-reviewed publication European Respiratory Journal.

The study highlights the effect of inhaled GB0139 in IPF patients on the plasma levels of highly relevant disease biomarkers, in particular YKL-40 and CCL-18, which have been shown to have prognostic significance in IPF (YKL-40 linked to IPF mortality and CCL-18 linked to fall in lung function – FVC). These and several other biomarkers (PDGF-B, PAI-1, Galectin-3) were reduced in a dose dependent fashion from baseline in a consistent and statistically significant manner, with the strongest effects in the 10 mg dose group compared to placebo.

Hans Schambye, CEO of Galecto, said: “We are excited that the study showed that with intervention with our inhaled small molecule therapy GB0139 in the lungs of IPF patients, we see fast onset and major reduction in a series of biomarkers known as drivers of lung fibrosis and linked to IPF mortality. GB0139’s concerted and marked impact on these biomarkers support its potential to make a significant difference in the treatment of IPF, and we are looking forward to advancing it further through clinical development and potentially to market.”

GB0139, an inhaled small molecule inhibitor of galectin-3, a protein known to play a central role in fibrosis in several organs, has received Orphan Drug Designation (ODD) from both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of IPF. The EMA cited clinically relevant biomarker data, in particular the significant reduction of YKL-40 in IPF patients, as a justification for the ODD designation. GB0139 was shown to be safe and well tolerated in healthy subjects and IPF patients in the phase 2a trial, and dose dependently suppressed expression of galectin-3, a protein known to play a central role in fibrosis in several organs, on alveolar macrophages.

“The availability of multiple biomarkers of IPF pathogenesis means physicians can not only monitor the progression of disease but also differentiate the effects of different treatments. The lockstep reduction in five biomarkers – PDGF-BB, PAI-1, Galectin-3, CCL18 and YKL-40 – in patients treated with TD139, but not with placebo, is an encouraging early sign that will require clinical confirmation,” said Toby Maher, one of the authors of the paper and Professor at Royal Brompton Hospital, Imperial College London and University of Southern California.

Galecto is now investigating GB0139 (formerly TD139) in the Phase 2b/3 GALACTIC-1 clinical trial in IPF. The trial is a pivotal size, randomized, double-blind, multicenter, parallel, placebo-controlled study across more than 100 centers in the U.S., the EU, and Canada, designed to evaluate the efficacy and safety of GB0139 in 450 subjects with IPF over 52 weeks.

About Galecto
Galecto is a clinical stage biotechnology company with advanced programs in fibrosis and cancer centered on galectin-3 and LOXL2. The company’s pipeline includes an inhaled galectin-3 modulator currently in phase 2b for the potential treatment of idiopathic pulmonary fibrosis, as well as two assets about to move into phase 2 targeting myelofibrosis, NASH and oncology. The Company is incorporated in the U.S. and has its operating headquarters in Copenhagen, Denmark.

Further information can be found at 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 focus, GB0139’s potential, plans for clinical development 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 and their therapeutic potential, having adequate funds and their use, and those disclosed in Galecto’s filings with the Securities and Exchange Commission, including its Registration Statement on Form S-1. 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.
For more information, contact:

Galecto Inc.
Hans Schambye, CEO
Jon Freve
+45 70 70 52 10
info@galecto.com

LifeSci Advisors (media)
Mary-Ann Chang
+44 7483 284 853
mchang@lifesciadvisors.com