Galecto Announces Positive Preliminary Results for Oral Galectin-3 Inhibitor GB1211 in Part 1 of its Phase 1b/2a Liver Cirrhosis Trial

December 13, 2021

GB1211 observed to be safe and well tolerated in initial twelve randomized subjects, including six hepatically impaired liver cirrhosis patients

Galecto initiates Part 2 of Phase 1b/2a trial in patients with liver cirrhosis

BOSTON, Dec. 13, 2021 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a publicly listed company focused on the development of novel treatments for fibrosis and cancer, today announced that it has successfully completed Part 1 of its Phase 1b/2a GULLIVER-2 trial, assessing the safety, tolerability and pharmacokinetics of the oral galectin-3 inhibitor GB1211 in patients with moderate hepatic impairment (Child-Pugh class B) as compared to healthy volunteers. GB1211 was observed to be well-tolerated, there were no drug-related serious adverse events, and exposure was only moderately increased in the Child-Pugh class B patients. Accordingly, no dose adjustment is required for Part 2 of the trial in patients with moderate hepatic impairment.

Galecto has also initiated Part 2 of the trial, which is a randomized, double-blind placebo-controlled trial designed to assess the effect of 12-week dosing of GB1211 on a wide series of biological markers of hepatic function and structure in participants with moderate hepatic impairment. The Phase 1b/2a GULLIVER-2 trial is the first in Galecto's clinical program for GB1211 in liver cirrhosis. Liver cirrhosis represents a significant unmet medical need for which there is no currently approved disease modifying therapy.

"Completing Part 1 of the GULLIVER-2 trial and initiating upon Part 2 is an important step forward in our development of GB1211 for liver cirrhosis," said Dr. Hans Schambye, CEO of Galecto. "We are very encouraged by the initial safety findings and favorable interim exposure data seen in Part 1 of the trial. We look forward to completing Part 2 of the trial in 2022, where we hope to demonstrate biomarker and clinical activity of GB1211. We remain on track to report top line data from the full trial in the second half of 2022."

The GULLIVER-2 trial (NCT05009680) is designed to assess the safety, tolerability, pharmacokinetics and potential activity of GB1211 in up to 54 participants, including liver cirrhosis patients with moderate or severe hepatic impairment (Child-Pugh classes B and C). In Part 2 of the trial, Child-Pugh class B liver cirrhosis patients of any etiology will be randomized to evaluate the impact of GB1211 on liver fibrosis and liver function.

Galectin-3 plays a key role in fibrosis development through cellular activation and the production of collagen, and Galecto has demonstrated that inhibiting the galectin-3 target with GB1211 reduces fibrosis in multiple animal models including models of liver fibrosis. Galectin-3 is elevated in cirrhosis patients and is a prognostic biomarker of hepatocellular carcinoma, a known complication of liver cirrhosis.

It is estimated that more than 100 million patients suffer from liver cirrhosis worldwide and the mortality rate is high. There are no approved disease modifying therapies and liver transplantation remains the sole option for late stage liver cirrhosis.

About GB1211
Galecto is developing GB1211, a proprietary orally available potent small molecule galectin-3 inhibitor. GB1211 has the potential to treat multiple types of cancer and fibrotic diseases. Galecto's initial target indications for GB1211 are NSCLC, a cancer indication with a high unmet need, and liver cirrhosis, a severe, progressive disease that ultimately leads to liver failure.

GB1211 demonstrated an anti-cancer effect and antifibrotic activity in multiple preclinical models and has successfully completed a Phase 1 trial in 78 healthy volunteers. In the Phase 1 trial, GB1211 was well-tolerated and had dose-dependent pharmacokinetics.

About Galectin-3 in Liver Cirrhosis
Galectin-3 has been shown to play a central role in fibrotic diseases, including liver cirrhosis. Preclinical evidence suggests that galectin-3 is required for TGF-beta-mediated activation of myofibroblasts and subsequent matrix production in liver fibrosis. Inhibition of galectin-3 reduces YKL-40, a chitin-like glycoprotein biomarker of liver fibrosis, and reduces the development of fibrosis.

About Galecto
Galecto is a clinical stage company incorporated in the U.S. that is developing pioneering 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 2 trial for the treatment of myelofibrosis; (iii) an orally active galectin-3 inhibitor (GB1211) in a phase 1b/2a trial in liver cirrhosis and expected to be evaluated in a phase 2 trial for the treatment of NSCLC in combination with an anti-PD1/-L1 product.

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 efficacy of GB1211; the timing of initiating clinical trials and providing topline data for Galecto's product candidates, including GB1211 in the GULLIVER-2 trial; and Galecto's 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 Galecto's most recent Annual Report on Form 10-K, filed with the SEC on March 29, 2021. 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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Source: Galecto, Inc.