Galecto Completes Enrollment in Phase 1b/2a GULLIVER-2 Trial of its Selective, Oral Galectin-3 Inhibitor GB1211 in Liver Cirrhosis

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Top-line results from GULLIVER-2 trial on track for the fourth quarter of 2022

Part 1 of GULLIVER-2 trial completed with positive results as previously announced in December 2021

BOSTON, March 29, 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 in Parts 2 and 3 of its ongoing 3-part Phase 1b/2a trial of GB1211, GULLIVER-2, in liver cirrhosis.

GB1211 is a selective, oral small molecule inhibitor of galectin-3 being studied in liver cirrhosis, a severe, progressive disease that ultimately leads to liver failure, and for which there are limited treatment options. GULLIVER-2 is an innovative hybrid trial, combining a hepatic impairment trial of safety, tolerability and pharmacokinetics (Parts 1 and 3) and a Phase 2 trial to examine safety and demonstrate effects of GB1211 on hepatic function, inflammation, coagulation and fibrosis (Part 2). This novel trial design is intended to provide a holistic view of the safety, pharmacokinetics, liver function and liver-related parameters of GB1211 in this vulnerable patient population with significant unmet needs.

- **Part 1** of the GULLIVER-2 trial, which was designed to measure the pharmacokinetics of GB1211 in patients with moderate hepatic impairment (**Child-Pugh class B**) as compared to healthy volunteers, was completed in December 2021. GB1211 was found to be well-tolerated with no drug-related serious adverse events.
- **Part 2** of the trial is a randomized, double-blind, placebo-controlled cohort in 30 patients with liver cirrhosis and moderate hepatic impairment (**Child-Pugh class B**). This part of the trial is designed to observe the safety and tolerability of GB1211 over 12 weeks while also measuring fibrosis biomarkers, hepatic function, inflammation, and coagulation parameters, as well as detecting fibrosis using transient elastography ultrasound.
- **Part 3** of the trial is an open-label cohort in 6 patients with severe hepatic impairment (**Child-Pugh class C**) and 6 matched healthy volunteers that is designed to examine the pharmacokinetics and safety and tolerability of GB1211.

“With Part 1 of the trial completed with encouraging initial safety findings and favorable interim exposure data, we are pleased to take another step forward in this important trial of our oral galectin-3 inhibitor, GB1211,” said Dr. Hans Schambye, President and Chief Executive Officer of Galecto. “Galectin-3 plays an important role in fibrosis development in the liver, and we have demonstrated GB1211 to be effective in protecting the liver cells and reducing fibrosis in animal liver models. As scientific advances for the treatment of liver cirrhosis have been very limited, galectin-3 inhibition may offer a new therapeutic possibility for patients with liver cirrhosis and related liver diseases. We look forward to presenting top-line results from the GULLIVER-2 trial in the fourth quarter of this year.”

Galectin-3 plays a key role in fibrosis development through cellular activation and collagen production, and Galecto has demonstrated that inhibiting the galectin-3 target with GB1211 protects liver cells and 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. Liver cirrhosis is associated with significant morbidity and mortality, and imposes a substantial health burden on many countries. It is estimated that more than 100 million patients suffer from liver cirrhosis worldwide. Currently, 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 exhibited dose-dependent pharmacokinetics.

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 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 a separate 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 tolerability and efficacy of GB1211, that the GULLIVER-2 trial will provide a holistic view of the safety, pharmacokinetics, liver function and liver-related parameters of GB1211, plans to release top-line results from the GULLIVER-2 trial in the fourth quarter of 2022; as well as Galecto’s general focus, plans for clinical development, 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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