Galecto Presents Positive Clinical Data at AASLD Showing Statistically Significant Improvements in Important Liver Parameters in Decompensated Cirrhosis Patients

November 8, 2022

- *Statistically significant reductions observed in ALT, AST and GGT, supporting further development of GB1211 in severe liver diseases*
- *Findings to be discussed in a conference call and virtual webinar today, November 8, 2022, at 8 a.m. ET*

BOSTON, Nov. 08, 2022 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a clinical-stage biotechnology company and a world leader in galectin biology focused on the development of novel treatments for fibrosis and cancer, announced it will discuss topline data and additional analyses from its recently completed Phase 1b/2a GULLIVER-2 trial (NCT05009680), including the observed statistically significant signs of liver protection, in a conference call and virtual webinar today, Tuesday, November 8th at 8:00 a.m. ET. The study was selected for a late-breaking oral presentation at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting® 2022.

Topline data showed statistically significant reductions in the liver enzymes ALT ($p<0.0005$), AST ($p<0.005$) and GGT ($p<0.05$), with encouraging reductions for ALP ($p<0.09$), after 12 weeks of treatment. GB1211 also demonstrated improvement and consistent signs of activity across biochemical liver function markers and markers of target engagement, apoptosis, and fibrosis, including reductions in galectin-3 ($p<0.05$) and CK-18 (M65) ($p<0.002$). Bilirubin, albumin, international normalized ratio (INR) and other biochemical measurements remained stable. These findings are unique even when compared to data from previous studies in patients with less severe liver disease and treated over longer periods of time, and suggest that GB1211 provided liver cell protection and improved liver status, further supporting clinical development in severe liver disease.

Dr. Michael Charlton, Professor of Medicine and Chief of Hepatology at the University of Chicago, commented, "This is the first study in a population of Child-Pugh Class B decompensated cirrhosis patients of non-viral etiology showing changes in a series of liver parameters that are potentially clinically meaningful. The values of several of these parameters improved further over time and were linked to a reduction in galectin-3, demonstrating target engagement. These results, coupled with a favorable tolerability profile, provide additional evidence that GB1211 merits further investigation and may offer a tolerable intervention in liver diseases."

Liver enzyme (AST, ALT, and GGT) reductions were observed after seven days of treatment and continued to decrease over the 12 weeks of treatment. These liver enzyme levels remained decreased compared to baseline two weeks after the study's conclusion, suggesting durable effects and a decrease in liver inflammation. The use of GB1211 in the GULLIVER-2 trial showed encouraging numerical improvements in liver health biomarkers after 12 weeks of therapy.

GB1211 exhibited a favorable tolerability profile in Child-Pugh B decompensated liver cirrhosis patients. Five of 15 patients on GB1211 and four of 15 patients on placebo reported nine and eight treatment-emergent adverse events (TEAEs), respectively. Three serious TEAEs were observed in one patient on GB1211, but were deemed to be unrelated to GB1211.

"We have now reported data from three separate clinical trials in IPF, COVID-19 and liver cirrhosis showing the benefits of galectin-3 inhibition. The GULLIVER-2 topline results indicate promising signs of clinical activity, suggesting that GB1211 could be an excellent therapeutic candidate for patients with severe liver disease," said Galecto CEO Hans T. Schambye, M.D., Ph.D. "Despite the substantial health burden that liver disease poses, scientific advances in therapeutics have been disappointing. There remains a significant need for disease modifying therapies that postpone or replace liver transplantation in late-stage liver cirrhosis patients. With these promising data in hand, we plan to conduct future studies that will explore the use of GB1211 in patients with liver disease."

The topline results from the GULLIVER-2 trial are aligned with the findings from Galecto's research of GB1211. Galectin-3 inhibition has demonstrated a marked reduction in liver enzymes (ALT, AST, and GGT) across several pre-clinical models, indicating a positive effect on liver function and a protection of the liver cells. Further, GB1211 reduced fibrosis in preclinical liver models, providing preclinical proof of concept for Galecto's approach to severe liver disease treatment. Additionally, there is a body of evidence that suggests high levels of galectin-3 are correlated with increasing severity of liver disease. Since galectin-3 is elevated in decompensated liver cirrhosis and is a prognostic biomarker of hepatocellular carcinoma (HCC), Galecto believes the inhibition of galectin-3 offers a viable therapeutic option in severe liver disease.

GULLIVER-2 Topline Data Webcast Information:

Galecto will host a live conference call and webcast at 8:00 am ET on Tuesday, November 8, 2022.

U.S. Dial-in Number:	1-877-300-8521
Int'l Dial-in Number:	1-412-317-6026
Conference ID:	10172584
Webcast:	Click HERE

The presentation and poster materials along with a replay of the call will be available on Galecto's investor relation's website at https://ir.galecto.com.

About Liver Disease
Liver diseases, including liver fibrosis or cirrhosis, are a global health burden. Cirrhosis – primarily caused by non-alcoholic steatohepatitis, alcoholic liver disease and hepatitis – is the end stage of progressive liver fibrosis and the leading cause of liver-related death globally.

About the GULLIVER-2 Trial
The GULLIVER-2 trial **(**NCT05009680) is a Phase 1b/2a trial designed to assess the safety, tolerability, pharmacokinetics and potential activity of GB1211 in up to 54 participants. This study includes patients with decompensated cirrhosis (**Child-Pugh Classes B and C**).

Part 2 of the GULLIVER-2 trial is a Phase 2, randomized, double-blind, placebo-controlled trial in 30 patients that is designed to assess the effect of 12-week repeated dosing of oral GB1211 on a wide series of markers of hepatic function and structure in patients with decompensated cirrhosis (**Child-Pugh B**). Patients are randomized 1:1 to receive oral GB1211 100mg or placebo twice daily for 12 weeks. Primary endpoints were safety and PK of GB1211. Secondary endpoints included assessment of GB1211 effect on liver clinical laboratory parameters, liver stiffness, and liver fat content, as measured by vibration controlled transient elastography (VCTE), and assessment of the model for end-stage liver disease (MELD) scores.

Parts 1 and 3 of the GULLIVER-2 trial are open-label, single dose study parts designed to evaluate the safety and pharmacokinetics of GB1211 in patients with moderate to severe hepatic impairment (**Child-Pugh B and C, respectively**) and compare with matched healthy subjects.

About GB1211
Galecto is developing GB1211, an orally available and potent small molecule galectin-3 inhibitor. Galecto's initial target indications for GB1211 are liver cirrhosis, a severe, progressive disease that ultimately leads to liver failure, and non-small cell lung cancer, a cancer indication with a high unmet need.

GB1211 demonstrated antifibrotic activity and anti-cancer effects in multiple preclinical models and has successfully completed a Phase 1 trial in 78 healthy volunteers. In the Phase 1 trial, GB1211 had a favorable tolerability profile 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 LOXL2. Galecto has four 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 (iv) an orally active galectin-3 inhibitor (GB1211) in a separate Phase 2 trial for the treatment of non-small cell lung cancer (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, that GB1211 may offer a tolerable intervention in moderate and severe liver diseases, 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 whether preliminary data that is reported herein changes following a more comprehensive review, the ongoing development of Galecto's product candidates and evaluation of their therapeutic potential, including emerging data on the safety profile of such candidates and their potential for disease-modifying activity, 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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