



Galecto Announces First Patient Treated in Phase 2 Trial of Oral Galectin-3 Inhibitor GB1211 in Liver Cirrhosis

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Galecto now has three ongoing Phase 2 clinical trials with three different drug candidates in three high value indications

BOSTON, Sept. 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 the first patient has been treated with the galectin-3 inhibitor GB1211 in the Phase 1b/2a GULLIVER-2 trial. This trial marks the initiation of Galecto's clinical program for GB1211 in liver cirrhosis. Top line data from the full trial is expected in the second half of 2022.

"We are very pleased with the continued momentum of our clinical programs and the start of this important study in liver cirrhosis," said Dr. Hans Schambye, CEO of Galecto. "The initiation of this trial follows our strategy of targeting indications with high unmet medical need based on solid biological evidence. Galecto now has three different drug candidates in three phase 2 clinical trials, highlighting the breadth of our product portfolio, and we plan to initiate a second Phase 2 trial of GB1211 in combination with a PD-1/L1 checkpoint inhibitor for the treatment of non-small-cell lung cancer (NSCLC) during the first half of 2022."

The GULLIVER-2 trial ([NCT05009680](#)) will assess the safety, tolerability, pharmacokinetics and efficacy of GB1211 in up to 54 participants, including liver cirrhosis patients with moderate or severe hepatic impairment (Child Pugh classes B and C). The trial will randomize liver cirrhosis patients of any etiology and 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. 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, an orally available potent 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 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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