



Galecto Publishes Results Showing Safety and Efficacy of the GB0139 Inhaled Galectin-3 Inhibitor in Hospitalized COVID-19 Patients on Standard of Care

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Results Support Favorable Safety and Tolerability Profile and Target Engagement of GB0139 and Potential for GB0139 in Severe Lung Disease

Company Provides Update on GALACTIC-1 Trial

BOSTON, Jan. 27, 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 the publication of the full results of an investigator-initiated open and randomized trial to evaluate Galecto's inhaled galectin-3 inhibitor, GB0139, in hospitalized patients with COVID-19 infection who required oxygen but not mechanical ventilation, compared to patients only on standard of care.

Galectin-3 plays a key role in COVID-19-related acute lung injury, cytokine storm, T-cell exhaustion and organ micro-thrombosis, and the results from this trial suggest that GB0139 has the potential for treatment of viral induced acute respiratory distress syndrome (ARDS) and acute lung injury (ALI).

The study met its primary endpoint of safety as there were no observed treatment-related adverse events. Despite patients having a mean age of 65 years, mean BMI of 32, multiple comorbidities, and being breathless, all patients were able to effectively inhale GB0139 and achieve pharmacologically relevant plasma levels. Target engagement was confirmed with a statistically significant reduction ($p < 0.01$) in serum galectin-3 levels.

The study showed that GB0139 on top of standard of care (which included treatments such as steroids, heparin, remdesivir and tocilizumab) may rapidly decrease markers of inflammation linked to the cytokine storm, inflammation-associated micro-thrombosis and those of short or long-term fibrosis. Patients treated with GB0139 had a significantly greater rate of decline in oxygen requirement versus standard of care alone and showed other signs of reduced organ damage. These effects were further accentuated in a subgroup of patients with moderate-to-severe disease who were at higher clinical risk. These patients showed multiple signs of improved immune-mediated viral responses as well as decreased lymphocyte exhaustion and decreased level of profibrotic macrophages. A 21% reduction of mortality was observed in this subgroup of patients at high clinical risk.

Professor Bertil Lindmark, Chief Medical Officer of Galecto, stated, "We are excited that the results of this study showed that GB0139 was biologically active and safely administered at high doses (20mg and 10mg) to patients with severe lung disease and difficulties breathing. Galectin-3 inhibition prevents key escalation steps of the viral-induced inflammatory response, including inflammation related thrombosis, and the processes of acute and chronic fibrosis. These novel findings enhance our conviction for the potentially wide medical applicability of our expanding portfolio of galectin-3 inhibitors."

Dr. Hans Schambye, President and Chief Executive Officer of Galecto, commented, "The published results further demonstrate the positive impact of galectin-3 inhibition in patients with severe lung disease. The safety and tolerability profile of GB0139 in patients with compromised lung function is encouraging, and we believe suggests additional potential in virus-induced acute lung injury. Given these exciting data, we plan to explore co-development opportunities with GB0139 for the treatment of COVID-19 and other severe viral lung diseases. Furthermore, the data from this study aligns with our findings in our IPF clinical trials completed to date and reaffirms the potential efficacy of GB0139 in our ongoing GALACTIC-1 trial."

The GALACTIC-1 trial is a Phase 2b, 52-week randomized, double-blind, multicenter, parallel, placebo-controlled trial investigating the safety and efficacy of GB0139 (3mg) in patients with IPF, with the rate of decline of forced vital capacity (FVC) as the primary endpoint. Based on blinded FVC (lung function) data from patients in this trial, the Company has determined that it may be possible to demonstrate a meaningful effect with fewer than the planned target of up to 210 randomized patients. As a result of this statistical analysis, the Company plans to seek regulatory approval of a protocol amendment to reduce the target patient population for the GALACTIC-1 trial, which would enable Galecto to maintain the cost structure of the trial and report topline results in mid-2023, as previously reported.

The research article is titled "*GB0139, an inhaled small molecule inhibitor of galectin-3, in COVID-19 pneumonia: A randomised, controlled, open-label, Phase 2a experimental medicine trial of the safety, pharmacokinetics, and potential therapeutic value.*" It is available through [the medRxiv preprint server](#) and has not yet been peer-reviewed. Galecto has submitted the article to a peer-reviewed publication and has had an abstract of the trial results accepted for presentation at the 2022 American Thoracic Society (ATS) Conference in San Francisco, CA from May 13-18, 2022.

COVID-19 Trial

In this open-label trial (<https://clinicaltrials.gov/ct2/show/NCT04473053>), 41 patients were randomized to receive either standard of care, which included treatments such as steroids, heparin, remdesivir and tocilizumab (n=21), or inhaled GB0139 (dosed at 10 mg twice a day for 2 days and subsequently once a day for up to 14 days) plus standard of care (n=20), to evaluate the safety and tolerability of GB0139, pharmacokinetics, and its effects on clinical outcomes and biomarkers. Patients had a mean age of 65 years, mean BMI of 32, multiple comorbidities, and were hospitalized and needed oxygen therapy, but did not require mechanical ventilation.

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 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 GB0139 in COVID-19 lung inflammation; that GB0139 may reduce lung fibrosis seen in COVID-19 patients; that GB0139 has the potential to counter the cytokine storm, inflammation-associated thrombosis, short and long-term fibrosis and multi-organ damage; the GALACTIC-1 trial, including plans for continuing to enroll patients and working with regulatory authorities to amend the protocol for the trial; that Galecto intends to submit the research article to a peer reviewed publication; 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 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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