Galecto's GB0139 Shows Favorable Safety and Tolerability Profile with Promising Changes in Efficacy Markers in Hospitalized COVID-19 Patients

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- *GB0139 significantly reduced oxygen flow requirements and improved several biomarkers for lung and systemic inflammation, liver function, tissue damage and coagulation*
- *Data demonstrate potential of GB0139 in patients with viral-induced acute lung injury*
- *Currently Galecto will prioritize resources for its four phase 2 trials in fibrosis and cancer*

BOSTON and COPENHAGEN, Denmark, June 22, 2021 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a publicly listed, clinical stage biotechnology company focused on the development of novel treatments for fibrosis and cancer, today announced preliminary topline results from an investigator-initiated trial examining Galecto's inhaled galectin-3 inhibitor (GB0139). This trial included 41 hospitalized patients with COVID-19 infection who did not require mechanical ventilation, of which 20 were randomized to the GB0139 arm.

GB0139, dosed at 10 mg twice a day for 2 days and subsequently once a day for up to 14 days, showed a favorable safety profile with no treatment-related serious adverse events reported. GB0139 had a positive trend on acute lung injury related to COVID-19, as patients who received GB0139 showed signs of improved lung function with a significant decline in oxygen flow requirements compared to patients only receiving standard of care (SOC), which included dexamethasone, remdesivir and anticoagulant therapy.

GB0139 showed target engagement by reducing galectin-3 levels compared to SOC ($p < 0.01$). Patients with COVID-19 were able to inhale GB0139 and achieve consistent exposure of GB0139 at levels previously associated with systemic biomarker responses in IPF patients (including YKL-40 and PAI-1). Patients showed improved inflammation and coagulation biomarkers, including CXCL10, thrombocytes and reduced D-dimers, as well as improved biomarkers of liver function and tissue damage. While the severity of the disease at baseline was worse in patients receiving GB0139, these patients had similar outcomes to patients receiving only SOC.

Bertil Lindmark, Chief Medical Officer of Galecto, stated, "Galectin-3 has been linked to several disease mechanisms in COVID-19 that correlate to disease severity. It is exciting to see improvements in anti-inflammatory, anti-thrombotic and organ function parameters over and above those seen in SOC. This illustrates the potential of galectin-3 inhibition in patients with acute lung injury and supports further assessment of GB0139 in viral-induced acute lung injury, including that caused by COVID-19."

In a post-hoc subgroup analysis of patients with moderate to severe COVID-19 infection, there was a 21% reduction in mortality in patients treated with GB0139 vs SOC. Furthermore, patients had reductions in CXCL10, IL-6, IL-10 and TNFα, suggesting that GB0139 has the potential to counter the cytokine storm and prevent acute respiratory distress syndrome and multi-organ failure. GB0139 also reduced PAI-1 and YKL-40 levels – as previously observed in Galecto's phase 2a trial in IPF patients. These markers are associated with a high risk of thrombosis and fibrosis, suggesting that GB0139 may reduce lung fibrosis seen in COVID-19 patients. This data together suggests GB0139 could result in clinical improvement in moderate to severe COVID-19 patients by reducing inflammation, improving lung and other organ function and reducing the risk of cytokine storm and micro-thrombosis.

Dr. Hans Schambye, President and Chief Executive Officer of Galecto, commented, "We were pleased that the safety and tolerability of GB0139 10 mg was further confirmed with early biomarker signs, which are in line with our previously reported IPF data. It is highly encouraging that we have now demonstrated in two separate clinical trials, IPF and COVID-19, that GB0139 can be dosed in patients with compromised lung function, and that the compound shows target engagement and highly relevant biological effects. Given the continued evolution of the COVID landscape, we believe that it is prudent to focus our financial and human resources on our exciting phase 2 pipeline of fibrosis and cancer treatments, including IPF, myelofibrosis, NSCLC and liver cirrhosis." Dr. Schambye added, "We will continue to pursue opportunities relating to viral-induced acute lung injury and also explore external options for partnering and/or funding additional COVID-19 activities."

It is anticipated that additional data from this trial will be released at a scientific conference later in 2021.

COVID-19 Trial
In this open-label trial (https://clinicaltrials.gov/ct2/show/NCT04473053), 41 patients were randomized to receive either standard of care 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, to evaluate the safety and tolerability of GB0139, pharmacokinetics, and its effects on clinical outcomes and biomarkers.

About Galecto
Galecto is a clinical stage biotechnology company incorporated in the U.S. that is developing small molecule-based galectin inhibitors and the collagen cross-linking enzyme, LOXL2, inhibitors. Galecto has multiple clinical programs in fibrosis and cancer focused on galectin-3 and LOXL2, including an inhaled galectin-3 modulator (GB0139) currently in a phase 2b trial for the potential treatment of idiopathic pulmonary fibrosis. The company's pipeline also includes an orally active galectin-3 inhibitor (GB1211) that is expected to be part of (i) a phase 2 trial for the potential treatment of NSCLC in combination with an anti-PD1 product and (ii) a phase 1b/2 trial in liver cirrhosis, as well as an orally active LOXL2 inhibitor (GB2064) that is expected to part of a phase 2 trial for the potential treatment of myelofibrosis. It is anticipated that enrollment for all of these trials will be initiated in 2021.

GB0139
GB0139 is the world's first small molecule galectin-3 inhibitor studied in man. The compound is not taken up via the oral route and is being developed as an inhaled therapeutic in Idiopathic Pulmonary Fibrosis (https://clinicaltrials.gov/ct2/show/NCT03832946). Early phase studies have shown that inhalation of GB0139 in healthy volunteers and in IPF patients is well tolerated, and the phase 2a IPF study showed significant effects on several biomarkers linked to worse outcomes in IPF.

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; the potential of galectin-3 inhibition in patients with acute lung injury; that GB0139 may reduce lung fibrosis seen in COVID-19 patients; that GB0139 has the potential to counter the cytokine storm and prevent acute respiratory distress syndrome and multi-organ failure; 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. 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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