Galecto, Inc. Receives U.S. and EU Orphan Drug Designations for GB0139 in Idiopathic Pulmonary Fibrosis

August 27, 2020

- The EMA cited GB0139's clinically relevant biomarker data in IPF patients
- Significant reduction of YKL-40 biomarker in fibrosis, inflammation, tissue remodeling diseases

Boston, MA/Copenhagen, Denmark, August 27, 2020 – Galecto, Inc., a privately-held biotechnology company focused on the development of novel treatments for fibrosis and cancer, today announced it has received Orphan Drug Designation (ODD) from both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for GB0139 in the treatment of Idiopathic Pulmonary Fibrosis (IPF).

The EMA cited clinically relevant biomarker data in IPF patients as a justification for the ODD designation, which provides financial incentives to encourage the development of drugs to treat rare diseases. In particular, GB0139 showed a significant reduction of the chitinase-like protein YKL-40, a serum biomarker in diseases with fibrosis, inflammation, and tissue remodeling, as well as other biomarkers relevant to IPF in its first in a human clinical study in IPF patients after 14 days of treatment. No changes in YKL-40 were reported in a study of patients being treated with the currently approved treatments pirfenidone and nintedanib, alone or in combination.

"We are very pleased that our promising GB0139 product candidate has received orphan drug designation in these two major markets, the U.S. and EU," said Hans Schambye, CEO of Galecto. "In particular, we are very encouraged that the EMA has cited our data, showing a higher effect on IPF biomarkers than the currently approved treatments, as a clinically relevant advantage. Our Phase 2b study in IPF is progressing well, and we look forward to bringing GB0139 further through clinical trials and potentially to market to address a significant unmet medical need."

GB0139 (formerly TD139) is an inhaled small molecule inhibitor of galectin-3, a protein known to play a central role in fibrosis in several organs. The company is investigating GB0139 in its Phase 2b GALACTIC-1 clinical trial in IPF. The trial is a randomized, double-blind, multicenter, parallel, placebo-controlled Phase 2b study across more than 100 centers in the U.S., the EU, and Canada, designed to evaluate the efficacy and safety of GB0139 in 450 subjects with IPF.

About Galecto

Galecto is a clinical stage biotechnology company with advanced programs in fibrosis and cancer centered on galectin-3 and LOXL2. The company's pipeline includes an inhaled galectin-3 modulator currently in phase 2b for the potential treatment of idiopathic pulmonary fibrosis, as well as two assets about to move into phase 2a targeting NASH and myelofibrosis. The company is incorporated in the U.S. and has its operating headquarters in Copenhagen, Denmark. Galecto is funded by Novo Holdings, OrbiMed, Ysios, HBM Healthcare Investments, Sunstone Capital, M Ventures, Bristol-Myers Squibb, Maverick Ventures, Seventure and SEED Capital.

Further information can be found at www.galecto.com.

For more information, contact:

Galecto Inc.
Hans Schambye, CEO
+45 26 3737 26
info@galecto.com

LifeSci Advisors (media)
Hans Herklots
+41 79 598 7149
hherklots@lifesciadvisors.com