

Galecto Provides Enrollment Update on Phase 2a MYLOX-1 Trial and Reiterates Expected Timing of Multiple Data Readouts in 2022

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Company has enrolled 10 of the targeted 16 patients in the trial

Anticipates interim data in mid-2022 and topline data from full trial in 2H 2022

BOSTON, Dec. 20, 2021 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a publicly listed company focused on the development of novel treatments for fibrosis and cancer, today announced it has enrolled 10 of the anticipated 16 patients in its Phase 2a trial of its oral LOXL2 inhibitor GB2064 in myelofibrosis.

The open label MYLOX-1 trial (NCT04679870) is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of orally administered GB2064 in 16 patients over 9 months. The trial will also assess the impact on fibrosis and quantification of the tissue targeting of GB2064, as well as other aspects of clinical response in myelofibrosis.

"We are very pleased to have enrolled over half of the targeted 16 patients in our MYLOX-1 trial. We are proud that the Galecto team continues to drive our clinical trials forward despite the challenging recruiting environment during the ongoing COVID-19 pandemic. We remain on track to report interim data in mid-2022 and topline data from the full trial in the second half of 2022," said Dr. Hans Schambye, CEO of Galecto. "We expect a data rich year in 2022 as we also anticipate reporting topline data from Part 2 of our liver cirrhosis GULLIVER-2 trial next year."

Myelofibrosis is a type of bone marrow cancer that causes scarring in the bone marrow and disrupts the body's normal production of blood cells, which can lead to multiple negative impacts and a significantly reduced quality of life and mortality.

LOXL2 is an enzyme that plays a key role in myelofibrosis and contributes to the fibrotic progression in this disease. Galecto's LOXL2 inhibitor, GB2064, has demonstrated potent inhibition of LOXL2 activity in cell-based assays and preclinical models and has successfully completed Phase 1 studies in healthy volunteers.

About GB2064

GB2064 is a pseudo-irreversible inhibitor of the LOXL2 enzyme, which means that high plasma concentrations will cancel the enzyme for a disproportionately longer time than the presence of the drug in plasma. This may mean that the risk of potential side effects due to drug remaining in the system could be reduced. GB2064 has been tested in healthy volunteers without finding dose limiting or dose-related tolerability issues.

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 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 timing of initiating clinical trials and providing topline data for Galecto's product candidates, including GB2064 in the MYLOX-1 trial and 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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