Galecto Announces First Patient Enrolled in Phase 2 Trial of GB1211 in Combination with Atezolizumab for First-Line Treatment of NSCLC

June 16, 2022

GB1211, Galecto's galectin-3 inhibitor, has shown potent anti-tumor effects and increased efficacy of checkpoint inhibition in pre-clinical models

BOSTON, June 16, 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 that the first patient has been enrolled in the Phase 2a GALLANT-1 trial (NCT05240131). GALLANT-1 is designed to study the combination of GB1211, Galecto's oral small molecule galectin-3 inhibitor, with Roche's PD-L1 checkpoint inhibitor, atezolizumab (Tecentriq®), for the first-line treatment of non-small cell lung cancer (NSCLC). Galecto anticipates topline data from GALLANT-1 in mid-2023.

The initiation of GALLANT-1 continues Galecto's strategy to treat cancer and fibrotic diseases through developing targeted therapeutics. Galectin-3, the target of GB1211, is elevated in many cancers. Increased galectin-3 expression in tumors is linked to tumor growth, invasiveness and metastatic potential. Furthermore, increased levels of galectin-3 in the tumor microenvironment facilitates tumor escape from the immune response by suppressing essential T-cell functions and activating tumor-protecting macrophages. Clinical evidence from patients with NSCLC suggests that high levels of galectin-3 in tumors leads to resistance to treatment with checkpoint inhibitors. In multiple pre-clinical models, including NSCLC, GB1211 has been shown to reduce tumor growth and metastasis and increase efficacy of checkpoint inhibition.

"As a leader in developing therapies using galectin inhibitors, we are very excited about the potential use of our proprietary compounds in difficult-to-treat cancers. GB1211 has been shown to be a well-tolerated, potent inhibitor of galectin-3 with the potential to act as a monotherapy in solid tumors and enhance checkpoint inhibitor therapies," said Dr Hans Schambye, CEO of Galecto. "Starting in the first-line treatment of NSCLC opens the door for Galecto to pursue numerous oncology opportunities."

The Phase 2a trial of GB1211 in combination with Tecentriq® will be a 1:1 randomized, double blind, placebo-controlled trial in patients with NSCLC in the first line setting. Part A of GALLANT-1 will be an open-label stage in 8-12 patients to select the dose of GB1211 (200mg or 400mg twice daily) to be used with Tecentriq®. Part B will evaluate safety and tumor shrinkage in up to 75 patients; additionally, it will explore tumor response rate based on RECIST criteria, clinical activity and immune biomarkers. Galecto is the sponsor of the study and Roche will provide clinical supply of Tecentriq®. Galecto retains all rights to GB1211 globally.

About GB1211 and Galectin-3 Mechanisms in Cancer
Increased galectin-3 expression in tumors is linked to tumor growth, invasiveness and metastatic potential. In the tumor tissue, galectin-3 supports the creation of fibrosis, tumor proliferation, metastasis, and immune avoidance. Galectin-3 uses a host of mechanisms including, but not limited to, VEGF, TGF-β, TYRO3, and MER-TK to increase tumor growth and metastasis. Furthermore, increased levels of galectin-3 in the tumor microenvironment facilitates tumor escape from the immune response by suppressing essential T-cell functions and activating tumor-protecting macrophages. Galectin-3-mediated immune suppression is linked to the removal of the interferon-gamma gradient and immune exhaustion via binding to LAG3 and the T-cell receptor.

Further, recent data announced at the 2022 ASCO Annual Meeting suggest that galectin-3 can enhance PD-1 and PD-L1 binding and avert the interference of anti-PD-1/anti-PD-L1 therapies by blocking the binding of the antibodies to their respective targets. GB1211 is designed to counter these effects.

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 exhibited dose-dependent pharmacokinetics. The mechanism of action is specific inhibition of the carbohydrate recognition domain of galectin-3.

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 four 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 (iv) an orally active galectin-3 inhibitor (GB1211) in 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 potential safety and efficacy of GB1211 in combination with atezolizumab (Tecentriq®); the timing of initiating clinical trials and providing topline data for Galecto's product candidates, including GB1211 in NSCLC; and Galecto's focus and plans for clinical development of its product candidates and pipeline. Such forward-looking statements include statements about Galecto's 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 February 17, 2022. 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.

For more information, contact:

Galecto, Inc.
Hans Schambye, CEO
Jon Freve, CFO
+45 70 70 52 10

Investors/US
Ashley R. Robinson
arr@lifesciadvisors.com
+1 617 430 7577

Media/EU
Sandya von der Weid
svonderweid@lifesciadvisors.com
+41 78 680 0538

Source: Galecto, Inc.