Galecto Announces Clinical Collaboration with Roche for Phase 2 Trial of GB1211 in Combination with Atezolizumab in First Line Non-Small-Cell Lung Cancer

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Upcoming Phase 2 trial marks expansion of Galecto pipeline into oncology and provides opportunity for exploring the use of galectin-3 inhibitors in cancer

Additional information relating to Galecto's oncology programs will be provided at upcoming R&D Day on November 8, 2021

BOSTON, Nov. 02, 2021 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a publicly listed biotechnology company focused on the development of novel treatments for fibrosis and cancer, today announced that it has entered into a clinical trial supply agreement with Roche to explore the combination of GB1211, Galecto's oral galectin-3 inhibitor, with Roche's PD-L1 checkpoint inhibitor atezolizumab (Tecentriq®) in Galecto's planned Phase 2a trial in non-small-cell lung cancer (NSCLC). Galectin-3 has been identified as the guardian of the tumor microenvironment, driving cancer growth and allowing tumor cells to escape the immune mediated attack through the activation of, among other things, LAG-3. Galecto's planned NSCLC trial marks the first opportunity to demonstrate the anti-cancer effects of a potent and selective oral galectin-3 inhibitor.

Under the terms of the agreement, Galecto will fund and conduct a Phase 2a clinical trial to investigate the combination of GB1211, Galecto's potent and selective oral small molecule galectin-3 inhibitor, and Tecentriq for the treatment of first line NSCLC.

"Our galectin-3 asset, GB1211, has shown compelling anti-cancer effects in preclinical models, specifically in NSCLC tumors high in galectin-3 and resistant to anti-PD-1/-L1," said Dr. Hans Schambye, CEO of Galecto. "Galectin-3 inhibition has the potential to increase both T-cell function as a single agent and the efficacy of check-point inhibitors in NSCLC patients with high galectin-3 expression. We look forward to initiating our phase 2a combination study of GB1211 in NSCLC during the first half of 2022 and anticipate topline data from this trial in mid-2023."

Dr. Schambye continued, "This phase 2a trial of GB1211 further expands our scope into oncology. Many cancers use galectin-3 to avoid immune recognition through interaction with LAG-3, TGF-β, interferon gamma and K-Ras. We have shown that GB1211 is able to counter these effects and increase check-point inhibitor efficacy in cancer models. Therefore, we believe that our galectin-3 inhibitors could represent a new and exciting option to treat cancer with a low level of toxicity."

The phase 2a trial of GB1211 in combination with Tecentriq will be a 1:1 randomized, double blind, placebo-controlled trial in up to 70 patients with NSCLC in the first line setting. The trial is designed to evaluate safety and tumor shrinkage; additionally, it will explore RECIST tumor response, clinical activity and immune biomarkers. Galecto will be the sponsor of the study and Roche will provide clinical supply of Tecentriq. Galecto currently retains all rights to GB1211.

About GB1211
Galecto is developing GB1211, an orally available potent galectin-3 inhibitor. GB1211 has the potential to treat multiple types of cancer and fibrotic diseases. Galecto's initial target indications for GB1211 are NSCLC, a cancer indication with a high unmet need, and liver cirrhosis, a severe, progressive disease that ultimately leads to liver failure and for which there are limited treatment options.

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 had dose-dependent pharmacokinetics.

About Galectin-3 in Oncology
Galectin-3 is overexpressed in many tumors and supports tumor proliferation, metastasis and immune attack avoidance. Galectin-3 binds to macrophage Tyro-3, T-cell LAG3, interferon gamma and the K-Ras complex. By inhibiting the galectin-3 binding to these key molecules and cells, an important direct effect can be achieved, similar to checkpoint inhibition, as well as a potential therapeutic synergy.

Clinical data in NSCLC has shown that patients with high tumor staining (>70%) with galectin-3 generally respond poorly to checkpoint inhibition. This biomarker could, if confirmed, offer a method to select patients in NSCLC and other tumors, which could increase the likelihood of response.

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 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®).

For more information, please 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 efficacy of GB1211 in combination with atezolizumab (Tecentriq®) in NSCLC patients; 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. 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, and other subsequent reports filed with the SEC. 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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