Galecto Presents Updated Clinical Data at ESMO Congress 2023 and Provides Update on Phase 1b/2a GALLANT-1 Trial

October 23, 2023

Partial response seen in three of five patients with advanced non-small cell lung cancer who received GB1211 100 mg plus atezolizumab for at least three weeks

BOSTON, Oct. 23, 2023 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a clinical-stage biotechnology company focused on the development of novel treatments for fibrosis and cancer, today presented a poster with new and encouraging clinical data, including two additional partial responders, from the dose-finding Part A of its Phase 1b/2a trial (NCT05240131) (the GALLANT-1 trial) at the European Society of Medical Oncology (ESMO) Congress 2023 in Madrid, Spain. The GALLANT-1 trial is designed to study the combination of atezolizumab (Tecentriq®) and GB1211, Galecto's first-in-class, oral small-molecule galectin-3 inhibitor candidate, in the first-line treatment of patients with metastatic/advanced non-small cell lung cancer (NSCLC).

At the recommended Phase 2 dose level of 100 mg GB1211 twice daily, investigator-assessed objective tumor responses (defined as partial responses per RECIST criteria 1.1) were observed in three of five patients (60%) who received GB1211 for at least three weeks. Response rates of only 22–38% have been observed with atezolizumab monotherapy in the first-line treatment of advanced NSCLC, suggesting a potential benefit of adding GB1211 to atezolizumab. The Company believes that GALLANT-1 is the first clinical trial to show that combining an oral galectin-3 inhibitor with a checkpoint inhibitor may enhance the effect of checkpoint inhibitors.

In addition, insights from early biomarker analyses revealed a trend showing that responders had increased levels of galectin-3 at baseline, and stable or decreasing galectin-3 levels during treatment. In contrast, patients with progressive disease demonstrated increasing levels of galectin-3 during treatment. This correlation suggests that the detection of galectin-3 levels could potentially be used to select and monitor patient populations.

Overall, the combination of GB1211 100 mg and atezolizumab appeared to be well-tolerated, with predominantly Grade 1 and Grade 2 treatment emergent adverse effects observed. At the 200 mg twice daily dose-level, two severe dose-limiting skin reactions were observed that may indicate lymphocyte activation in line with the GB1211 mode of action, which resulted in a reduction to the 100 mg GB1211 dose level. Importantly, these skin rashes were not observed at the recommended Phase 2 dose level of 100 mg GB1211 twice daily.

As part of Galecto's recently announced strategic alternative process, Galecto has determined that it will not initiate Part B of the GALLANT-1 trial and will instead reallocate its resources to focus on the treatment of severe liver diseases. Galecto will continue to supply GB1211 100 mg for the upcoming investigator-initiated Phase 2 trial at Providence Portland Medical Center's Earle A. Chiles Research Institute (EACRI). This trial, which is expected to be initiated in early 2024, will evaluate the safety and efficacy of GB1211 in combination with pembrolizumab (Keytruda®). Galecto plans to explore external options for partnering and/or funding additional oncology-focused activities for GB1211 as part of its strategic alternative process.

Following the poster presentation at the ESMO Congress, the poster will be available on the Scientific Conferences page of Galecto's investor relations website at https://ir.galecto.com/news-and-events/scientific-events.

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 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.

Evidence suggests 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.

About the GALLANT-1 trial
The Phase 1b/2a trial of GB1211 in combination with atezolizumab (Tecentriq®) was designed to be a randomized, double-blind, placebo-controlled trial in patients with NSCLC in the first-line setting. Part A of the GALLANT-1 trial was an open-label trial that determined the 100 mg dose of GB1211 to be the recommended dose in future oncology trials. Part B of the GALLANT-1 trial had been designed to evaluate safety and tumor shrinkage in NSCLC patients and explore tumor response rate based on RECIST criteria (version 1.1), clinical activity, and immune biomarkers.

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 Phase 2 clinical programs in fibrosis and cancer, including (i) an orally active LOXL2 inhibitor (GB2064) in a Phase 2a trial for the treatment of myelofibrosis; (ii) an orally active galectin-3 inhibitor (GB1211) in a recently completed Phase 1b/2a trial in liver cirrhosis; and (iii) an orally active galectin-3 inhibitor (GB1211) in combination with atezolizumab (Tecentriq®) in a separate Phase 2a trial for the treatment of NSCLC.

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; the timing of initiating clinical trials not being conducted by Galecto; 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, but not limited to, Galecto's Annual Report on Form 10-K, as filed with the SEC on March 9, 2023. 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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Source: Galecto, Inc.