Galecto's Galectin-3 Inhibitor GB1211 to be Studied in Combination with Pembrolizumab in Patients with Metastatic Melanoma and Head and Neck Squamous Cell Carcinoma by Providence Cancer Institute

October 19, 2022

Phase 2 investigator-initiated trial to be supported by an NCI grant to Providence Cancer Institute in Portland, Oregon to study a combination of pembrolizumab and a galectin-3 inhibitor

BOSTON, Oct. 19, 2022 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a clinical stage biotechnology company focused on the development of novel treatments for cancer and fibrosis, today announced that it has entered into a collaboration agreement for an investigator-initiated Phase 2 trial at Providence Portland Medical Center's Earle A. Chiles Research Institute (EACRI) to evaluate the safety and efficacy of GB1211, Galecto's first-in-class, oral small molecule galectin-3 inhibitor candidate, in combination with pembrolizumab (Keytruda ®). Galecto has committed to supply GB1211 for the Phase 2 trial.

Galectin-3 is overexpressed in many cancers, including melanoma and head and neck squamous cell carcinoma (HNSCC). 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 can cause checkpoint inhibitor resistance by blocking the binding of the checkpoint inhibitor antibodies, pembrolizumab and atezolizumab (Tecentriq®), to their respective targets. Preclinical data has shown that GB1211 has the ability to reduce galectin-3-induced checkpoint inhibitor blockages, thus preventing galectin-3 from inducing checkpoint inhibitor resistance.

Dr. William Redmond, Director, EACRI Immune Monitoring Lab, and co-principal investigator for the planned Phase 2 trial, stated, "We have published data on the important role of galectin-3 in the tumor microenvironment. We are excited to start this study in melanoma and HNSCC patients to potentially counteract checkpoint inhibitor resistance by combining pembrolizumab and GB1211."

"We are excited to launch this trial led by Drs. William Redmond and Brendan Curti. Dr. Redmond is a world leading expert on the role of galectin-3 in cancer and checkpoint inhibitor resistance and has demonstrated how galectin inhibition can be used to enhance tumor treatment," stated Dr. Hans Schambye, CEO of Galecto. "As we are already examining the use of GB1211 in a separate Phase 2 trial for the treatment of NSCLC in combination with atezolizumab, we are delighted to now have the opportunity to investigate the use of GB1211 with another leading checkpoint inhibitor, pembrolizumab. This new trial is an important step forward in expanding the reach of GB1211 into additional cancer indications, addressing the unmet needs in the treatment of metastatic melanoma and HNSCC."

The randomized, double-blind placebo controlled, investigator-initiated Phase 2 trial will evaluate whether the addition of GB1211 increases the response rate of pembrolizumab in metastatic melanoma and HNSCC patients. The study will employ a fixed dose of GB1211 in conjunction with the standard therapeutic dose of pembrolizumab in patients with unresectable or metastatic melanoma or recurrent or metastatic HNSCC progressing during or after platinum-containing chemotherapy. In addition to monitoring for toxicity and clinical response, blood and tumor samples will be obtained to assess immunologic measures relevant to galectin-3 biology and checkpoint inhibition. The Phase 2 trial is expected to begin in 2023 and top line results of the combination are expected to be reported as early as 2025.

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.

Preclinical data announced at the 2022 ASCO Annual Meeting furthermore 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 specifically designed to counter these anti-checkpoint inhibitor effects of galectin-3.

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.

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.

About Providence Cancer Institute
Providence Cancer Institute of Oregon, a part of Providence St. Joseph Health, offers the latest in cancer services, including diagnostic, treatment, prevention, education, support and internationally renowned research.

Providence Cancer Institute is home to the Earle A. Chiles Research Institute, a world-class research facility located within the Robert W. Franz Cancer Center in Portland, Oregon, and is a recognized leader in the field of cancer immunotherapy since 1993. Investigators lead more than 400 active clinical trials in key areas such as cancers of the breast, colon, prostate, lung, esophagus, liver and pancreas, head and neck, ovary, skin and blood. Other studies are investigating treatments for COVID-19. Learn more at providenceoregon.org/cancer.

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 pembrolizumab, the timing for initiation and readout of the investigator-initiated trial being led by Providence Cancer Institute 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.

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