Galecto Announces First Patient Dosed in an Investigator-Initiated Phase 2 Trial of GB1211 in Combination with Pembrolizumab

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An NCI-supported Phase 2 investigator-initiated trial at the Providence Cancer Institute in Portland, Oregon, has enrolled its first patient in a study exploring the combination of pembrolizumab (Keytruda®) and Galecto's GB1211, an oral galectin-3 inhibitor, in patients with metastatic melanoma and head and neck squamous cell carcinoma

BOSTON, May 01, 2024 (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 the first patient has been enrolled in an investigator-initiated Phase 2 trial to evaluate GB1211, Galecto's first-in-class, oral small molecule galectin-3 inhibitor candidate, at the Earle A. Chiles Research Institute (EACRI), a division of Providence Cancer Institute in Portland, Oregon, USA. Under the direction of Providence investigators Dr. Brendan Curti and Dr. William Redmond, the study aims to evaluate the safety and efficacy of GB1211 at a dose of 100mg twice daily in combination with pembrolizumab for the treatment of metastatic malignant melanoma (MM) and head and neck squamous cell carcinoma (HNSCC). Drs. Curti and Redmond received an R01 Research Project Grant award from the National Cancer Institute, National Institutes of Health, for their investigator-initiated Phase 2 trial. Galecto has committed to supply GB1211 for the trial.

Galectin-3 is overexpressed in many cancers, including melanoma and 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 associated interference with immune checkpoint inhibition (ICI), thus alleviating galectin-3-specific ICI resistance.

In the fourth quarter of 2023, Galecto reported topline results from its Phase 1b/2a GALLANT-1 clinical trial evaluating GB1211 twice daily in combination with atezolizumab for the first-line treatment of non-small cell lung cancer (NSCLC). Galecto reported that investigator-assessed objective tumor responses (defined as partial responses per RECIST criteria 1.1) were observed in three of five patients (60%) who received the recommended Phase 2 dose level of GB1211 100 mg for at least three weeks. Historically, 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 ICI.

Dr. Brendan Curti, Medical Director, Providence Melanoma Program, and EACRI Member and Robert W. Franz Endowed Chair for Clinical Research, said, "Our ability to perform bench-bedside research is a great strength of the Providence Cancer Institute. The insights from Dr. Redmond's lab about how to use galectin inhibitors to alter the tumor microenvironment and promote anti-tumor activity, as well as our initial observations in patients, provide a robust rationale for our phase II clinical trial in patients with melanoma and HNSCC."

Dr. William Redmond, Member and Director, EACRI Immune Monitoring Lab, and co-principal investigator for the trial, stated, "We have published a significant amount of data on the important role of galectin-3 in creating immune suppression within the tumor microenvironment. We are excited to start this study in melanoma and HNSCC patients to potentially counteract ICI resistance and increase the efficacy of ICI by combining GB1211 and pembrolizumab."

"We are excited that the Providence Cancer Institute and Drs. William Redmond and Brendan Curti have initiated this trial. Dr. Redmond is a world-leading expert on the role of galectin-3 in cancer and ICI resistance and has demonstrated how galectin inhibition can be used to enhance tumor treatment," stated Dr. Hans Schambye, CEO of Galecto. "Following the encouraging topline results from the GALLANT-1 trial that we reported in the fourth quarter of 2023, we look forward to exploring potential synergies with another leading ICI, pembrolizumab. This new trial marks a significant stride towards exploring GB1211's potential to enhance the effectiveness of ICI in various cancer indications."

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 MM or recurrent or metastatic HNSCC progressing during or after platinum-containing chemotherapy. In addition to monitoring for toxicity and clinical response, biospecimens will be obtained to assess immunologic measures relevant to galectin biology and T-cell checkpoint inhibition. Tumor volume will be assessed by immune response RECIST criteria (iRECIST criteria 1.1). It is anticipated that early data from this trial could be available 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 multiple Phase 2 clinical opportunities in fibrosis and cancer, including (i) an orally active LOXL2 inhibitor (GB2064) for the treatment of myelofibrosis; (ii) an orally active galectin-3 inhibitor (GB1211) for the treatment of liver cirrhosis; and (iii) an orally active galectin-3 inhibitor (GB1211) in combination with a checkpoint inhibitor for various oncology indications.

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. Learn more at www.providence.org/ORcancer.

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 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 March 8, 2024. 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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