Journal for ImmunoTherapy of Cancer Publishes Phase 1 Clinical Research Showing Belapectin, Galectin Therapeutics' Galectin-3 Inhibitor, Enhances Tumor Response in Combination with Anti-PD-1 Therapy

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Combination therapy with belapectin suggests a better objective response rate with fewer adverse events than pembrolizumab (KEYTRUDA®) alone

NORCROSS, Ga., April 13, 2021 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, today announced that a paper published in the peer-reviewed *Journal for ImmunoTherapy of Cancer (JITC),* the highest ranked fully open access immunology journal, provides further clinical evidence that using belapectin, a potent galectin-3 inhibitor, in combination with pembrolizumab (KEYTRUDA®), a PD-1 inhibitor, significantly enhances tumor response to immunotherapy in patients with advanced metastatic melanoma (MM) and head and neck squamous cell carcinoma (HNSCC).

The paper, titled "Enhancing Clinical and Immunological Effects of anti-PD-1 with Belapectin, a Galectin-3 Inhibitor" (doi:10.1136/jitc-2021-002371) describes results from an ongoing Phase 1 clinical study, a collaboration between Galectin Therapeutics and Providence Cancer Institute in Portland, Oregon.

Following the recent publication of positive preclinical results that showed the inhibition of galectin-3 in combination with an agonist anti-OX40 monoclonal antibody reprograms the tumor microenvironment to favor anti-tumor activity, the current study tests the clinical hypothesis that galectin-3 blockade with belapectin in combination with pembrolizumab enhances tumor response for patients with advanced MM or HNSCC.

In the study, as previously disclosed, an objective response was observed in 50% of MM (7/14) and 33% of HNSCC (2/6) patients. This compares favorably to published response rates on pembrolizumab alone. The authors noted that the combination was associated with fewer immune-mediated adverse events than anticipated with pembrolizumab alone. In addition, the analysis of patients' tumor tissue revealed reduced monocytic myeloid-derived suppressor cells and increased effector memory T-cell activation in responders compared with non-responders. Also, an increased baseline expression of galectin-3 positive tumor cells correlated with clinical response.

"Immunotherapy is a significant breakthrough in the treatment of many cancers, but tumor-induced immune suppression contributes to treatment resistance. Galectin-3 is an important driver of this tumor-induced immunosuppression, and this clinical study constitutes proof-of-concept that the addition of belapectin, a galectin-3 inhibitor, to a PD-1 inhibitor can benefit cancer patients," said Dr. Brendan Curti, M.D., Earle A. Chiles Research Institute, a division of Providence, and the first author of the paper.

"The analysis of patients' tumor tissues is consistent with previously published pre-clinical data with belapectin and confirms the ability of belapectin to modulate the tumor microenvironment to favor anti-tumor activity. The possibility to improve the tolerance and safety of immunotherapy is also very exciting," commented Pol F. Boudes, M.D., Chief Medical Officer of Galectin Therapeutics. "These proof-of-concept clinical data provide a strong rationale to initiate a randomized placebo-controlled phase 2 clinical trial to evaluate the efficacy and safety of belapectin in combination with a PD-1 inhibitor compared to a PD-1 inhibitor alone in this cancer patient population. We look forward to continuing our work with Providence Cancer Institute, and we anticipate the upcoming release of additional data from the expansion cohort in this study."

About Belapectin (GR-MD-02)

Belapectin (GR-MD-02) is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH and fibrosis. Galectin-3 plays a major role in diseases that involve scarring of organs including fibrotic disorders of the liver, lung, kidney, heart and vascular system. Belapectin binds to galectin-3 and disrupts its function. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis. A Phase 2 study showed belapectin may prevent the development of esophageal varices in NASH cirrhosis; these results provide the basis for the conduct of the NAVIGATE trial. The NAVIGATE trial (NAVIGATEnash.com), entitled "A Seamless Adaptive Phase 2b/3, Double-Blind, Randomized, Placebo-controlled Multicenter, International Study Evaluating the Efficacy and Safety of Belapectin (GR-MD-02) for the Prevention of Esophageal Varices in NASH Cirrhosis" began enrolling patients in June 2020 and is posted on www.clinicaltrials.gov (NCT04365868). Galectin-3 also has a significant role in cancer, and the Company is supporting a Phase 1 study in combined immunotherapy of belapectin and KEYTRUDA in treatment of advanced melanoma and in head and neck cancer.

About Galectin Therapeutics

Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver disease and cancer. Galectin's lead drug belapectin (formerly known as GR-MD-02) is a carbohydrate-based drug that inhibits the galectin-3 protein which is directly involved in multiple inflammatory, fibrotic, and malignant diseases, for which it has Fast Track designation by the U.S. Food and Drug Administration. The lead development program is in non-alcoholic steatohepatitis (NASH) with cirrhosis, the most advanced form of NASH-related fibrosis. This is the most common liver disease and one of the largest drug development opportunities available today. Additional development programs are in treatment of combination immunotherapy for advanced melanoma and other malignancies. Advancement of these additional clinical programs is largely dependent on finding a suitable partner. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. Additional information is available at www.galectintherapeutics.com.

About Providence Cancer Institute

Providence Cancer Institute, 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/rectum, 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

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future financial performance, and use words such as “may,” “estimate,” “could,” “expect” and others. They are based on management’s current expectations and are subject to factors and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include those regarding the hope that Galectin’s development program for belapectin will lead to the first therapy for the treatment of fatty liver disease with cirrhosis and those regarding the hope that our lead compounds will be successful in cancer immunotherapy and in other therapeutic indications. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that trial endpoints required by the FDA may not be achieved; Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of belapectin or any of its other drugs in development; the Company may not be successful in scaling up manufacturing and meeting requirements related to chemistry, manufacturing and control matters; the Company’s current NAVIGATE clinical trial and any future clinical studies as modified to meet the requirements of the FDA may not produce positive results in a timely fashion, if at all, and could require larger and longer trials, which would be time consuming and costly; plans regarding development, approval and marketing of any of Galectin’s drugs are subject to change at any time based on the changing needs of the Company as determined by management and regulatory agencies; regardless of the results of any of its development programs, Galectin may be unsuccessful in developing partnerships with other companies or raising additional capital that would allow it to further develop and/or fund any studies or trials. Galectin has incurred operating losses since inception, and its ability to successfully develop and market drugs may be impacted by its ability to manage costs and finance continuing operations. Global factors such as COVID-19 may limit access to NASH patient populations around the globe and slow trial enrollment and prolong the duration of the trial and significantly impact associated costs as well as impact other trial related activities including, amongst others, manufacturing and regulatory reviews. For a discussion of additional factors impacting Galectin’s business, see the Company’s Annual Report on Form 10-K for the year ended December 31, 2020, and subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

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