# OncoImmunology Publishes Pre-clinical Research Showing Galectin Therapeutics' Belapectin Galectin-3 Inhibitor Reduces Tumor Progression in Combination with Anti-OX40 Therapy

March 8, 2021

**Research deciphers belapectin's mechanism of action, further rationalizing its use in combination with checkpoint inhibitors or T cell agonists in oncology and as a monotherapy in NASH cirrhosis**

NORCROSS, Ga., March 08, 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 *OncoImmunology* demonstrates how belapectin, a potent galectin-3 inhibitor, in combination with an anti-OX40 (CD134) monoclonal antibody, significantly reduces tumor progression compared to either agent alone.

For many years, galectin-3 has been known to play a key role in the control of tumor-induced immunosuppression. Galectin-3 acts to maintain tumor growth, in part, by supporting the generation of suppressive macrophages and inhibiting T cell function.

The paper, titled "Galectin-3 inhibition with belapectin combined with anti-OX40 therapy reprograms the tumor microenvironment to favor anti-tumor immunity," describes results from a collaboration between Galectin Therapeutics and Providence Cancer Institute in Portland, Oregon. The paper highlights the mechanism of action of the combination which is explained by a reduction in myeloid-derived suppressor cell infiltration and function coupled to an increase in T-cell effector function. In tumor-bearing mice, these effects led to both tumor regression and improved survival.

"Immunotherapy represents a significant breakthrough in the treatment of many cancers. However, tumor-induced suppression could decrease response to anti-OX40 therapy," said senior author William L. Redmond, Ph.D., Associate Member, Laboratory of Cancer Immunotherapy, and Director, Immune Monitoring Laboratory at the Earle A. Chiles Research Institute, a division of Providence. "As galectin-3 drives this tumor-induced immunosuppression, it was an attractive hypothesis to combine belapectin with anti-OX40 immunotherapy. We demonstrated that the addition of belapectin could overcome this resistance and we were also able to decipher the underlying mechanism of action."

"This is very significant research," noted Pol F. Boudes, M.D., Chief Medical Officer of Galectin Therapeutics. "It further validates the rationale for the ongoing clinical research at Providence Cancer Institute, combining belapectin with pembrolizumab (Keytruda®), a programmed death receptor-1 (PD-1)-blocking antibody. Preliminary results indicated that the combination of Keytruda® and belapectin may improve the efficacy of this potent PD-1 inhibitor while also improving its tolerance."

Dr. Boudes added, "These data, demonstrating the essential role of cells of the monocytic macrophages lineage can also be translated to our ongoing belapectin clinical program in patients affected with NASH cirrhosis. In cirrhosis, as with the tumor microenvironment of cancer, activated macrophages invade the hepatic parenchyma and promote inflammation, fibrosis and ultimately the failure of this essential organ. Belapectin, thanks to its molecular structure, is uniquely able to target macrophages, which, incidentally, are also the main producer of galectin-3 in liver cirrhosis."

The *OncoImmunology* paper is now openly accessible online on the journal website and at galectintherapeutics.com/publications/.

**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, 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 NASH-RX 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, 2019, 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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