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Galectin Therapeutics' GR-MD-02 to be Studied in Combination With Keytruda(R) in Patients With Metastatic Melanoma

Providence Cancer Center Submits IND for Phase 1b Trial

NORCROSS, Ga., Oct. 19, 2015 (GLOBE NEWSWIRE) -- Galectin Therapeutics, Inc. (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announces that Providence Cancer Center has filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to study GR-MD-02 in combination with Keytruda® (pembrolizumab), an immune checkpoint inhibitor, in a Phase 1b study of patients with advanced refractory metastatic melanoma. GR-MD-02 binds to and inhibits galectin proteins, predominantly galectin-3 (Gal-3). Galectin will provide GR-MD-02 to the investigators, who are funding the costs of this study.

The IND filing was prompted by findings from preclinical studies led by tumor immunology expert William L. Redmond, Ph.D. of the Providence Cancer Center's Earle A. Chiles Research Institute. That study found that GR-MD-02 increased tumor shrinkage and enhanced survival in immune competent mice with multiple types of cancers when combined with one of the immune checkpoint inhibitors, anti-CTLA-4 or anti-PD-1. Pembrolizumab (anti-PD-1) was approved by the FDA in September 2014 to treat patients whose melanoma had progressed after treatment with Yervoy® (ipilimumab) or targeted therapy in melanomas that have a BRAF mutation. Details of the study design can be found at clinicaltrials.gov: here. GR-MD-02 is also the subject of an ongoing Phase 1b study in combination with Yervoy in patients with malignant melanoma, also by Providence Cancer Center.

"This proposed study will be the second involving a checkpoint inhibitor in combination with GR-MD-02, and we are very pleased to reach this milestone with the investigators at the Portland Cancer Center," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. "Preclinical data show that GR-MD-02 holds potential to increase the effectiveness of other therapies and represents a promising approach to enhance cancer immunotherapy."

Pending FDA review of the IND, the Phase 1b study will be conducted by the Providence Cancer Center under principal investigator Brendan D. Curti, M.D., director of the Providence Biotherapy Program. Providence Cancer Center researchers have been leaders in immunotherapy research and translational clinical trials in melanoma and other cancers.

"Clinical research has shown that therapeutic combinations involving checkpoint inhibitors have improved outcomes in patient survival. The Phase 1b study will determine if GR-MD-02 enhances the probability of melanoma response with pembrolizumab by inducing proliferation, activation and memory function of CD8+ T cells," said Dr. Curti. "The combination of GR-MD-02 and pembrolizumab has a strong scientific rationale based on Dr. Redmond's laboratory work. This study represents a novel approach for patients with metastatic melanoma and complements our similar study of GR-MD-02 in combination with Yervoy."

Study Design

The proposed Phase 1b study is expected to enroll 16 to 22 patients with advanced melanoma whose disease has progressed after treatment with ipilimumab and/or BRAF-targeted therapy in melanomas with a BRAF mutation, and is designed to determine a safe dose of GR-MD-02 in combination with the approved dose of pembrolizumab (2 mg/kg). The study will employ a 3+3 Phase 1 design with dose escalation of GR-MD-02 beginning with 2 mg/kg in the first cohort and increasing to 8 mg/kg, depending on toxicity. In addition to monitoring for toxicity and clinical response, blood samples will be obtained to assess immunologic measures relevant to galectin biology and pembrolizumab T-cell checkpoint inhibition. Galectin Therapeutics will supply researchers with supporting analysis of the pharmacokinetics of GR-MD-02 and the right to reference the Company's open IND on GR-MD-02.

Yervoy® is a registered trademark of Bristol-Myers Squibb. Keytruda® is a registered trademark of Merck.

About Metastatic Melanoma

Melanoma, the most dangerous form of skin cancer, is one of the most widespread cancers among young adults. Metastatic melanoma occurs when the cancer cells spread (or metastasize) through the lymph nodes to other parts of the body. The liver, lungs, bones and brain are most often affected by these metastases. The American Cancer Society estimates that there were more than 76,000 new diagnoses and 9,100 deaths from melanoma in the United States in 2012.

About Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute (EACRI), Providence Cancer

Center, Providence Portland Medical Center, Portland Oregon

Providence Cancer Center, a part of Providence Health & Services, offers the latest in cancer services, including diagnostic, treatment, prevention, education, support and internationally renowned research. The Robert W. Franz Cancer Research Center in the Earle A. Chiles Research Institute is a world-class research facility located within Providence Cancer Center. The Institute's main area of investigation is cancer immunotherapy, a specialized field of study focused on triggering the immune system to fight cancer. Visit www.providence.org/cancer.

About Galectin Therapeutics

Galectin Therapeutics is developing promising carbohydrate-based therapies for the treatment of fibrotic liver disease and cancer based on the Company's unique understanding of galectin proteins, which are key mediators of biologic function. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. The Company is pursuing a development pathway to clinical enhancement and commercialization for its lead compounds in liver fibrosis and cancer. Additional information is available at www.galectintherapeutics.com.

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 GR-MD-02 will increase the effectiveness of a checkpoint inhibitor in the treatment of advanced refractory metastatic melanoma. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that GR-MD-02 may not be safe or effective in combination with Keytruda or Yervoy. Moreover, Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of GR-MD-02 or any of its other drugs in development for the treatment of cancer, fatty liver disease with cirrhosis or other diseases. The Company's current clinical trials and any future clinical studies may not produce positive results in a timely fashion, if at all, and could prove 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. 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, 2014, 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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