

Combination Immunotherapy of Pembrolizumab with the Galectin-3 Inhibitor GR-MD-02 Shows Promising Early Results in Treatment of Advanced Melanoma from a Phase 1b Clinical Trial

11/13/17

The objective response rate in advanced melanoma was 62.5% (five of eight subjects)

NORCROSS, Ga., Nov. 13, 2017 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, and Providence Cancer Institute today announced the presentation of preclinical and early clinical data from an investigator-initiated Phase 1 clinical trial of GR-MD-02 used in combination with pembrolizumab (KEYTRUDA®). Data of two complimentary abstracts were presented Nov. 11, 2017 at the Annual Meeting of the Society for Cancer Immunotherapy in National Harbor, Md., by William L. Redmond, Ph.D., Earle A. Chiles Research Institute, a division of Providence Cancer Institute (data posted).

Three patients in cohort 2 (4 mg/kg GR-MD-02) have now been completed to add to the six patients in dose cohort 1 (2 mg/kg GR-MD-02). One patient in the first cohort had head and neck cancer, while the remaining eight patients had advanced melanoma. Five patients with advanced melanoma had objective responses after five courses of every three-week therapy, with three partial responses and two complete responses. All the patients in the second cohort had an objective response. Please refer to the posted data to review additional information on the patients who responded.

An infographic accompanying this release is available at <http://www.globenewswire.com/NewsRoom/AttachmentNg/29964758-bae9-4bc0-8155-fc11eda6e8e5>

"In addition to the encouraging clinical responses seen in this study, we are making progress on identifying immunological markers that may predict clinical responses to the combination therapy," said Redmond, associate member, Laboratory of Cancer Immunotherapy, and director, Immune Monitoring Laboratory. "In this regard, we have shown that clinical responders to the combination of GR-MD-02 and pembrolizumab may have reduced myeloid-derived suppressor cells following treatment."

The Providence Cancer Institute translational medicine team conducted two phase 1 clinical trials, initiated under direction of principal investigator Brendan D. Curti, M.D., director, Genitourinary Oncology Research and Immunotherapy Clinical Program, and co-director, Melanoma Program.

GR-MD-02 was also combined in an investigator-led trial with ipilimumab (Yervoy®) in patients with advanced melanoma (<https://clinicaltrials.gov/ct2/show/NCT02117362?term=GR-MD-02&rank=6>). Seven subjects treated with the lowest two dose cohorts of GR-MD-02 (1 and 2 mg/kg) have been completed with no safety signals identified due to GR-MD-02. In these low dose initial cohorts, there were no notable changes in the peripheral immune signature. Due to changes in the standard of care for metastatic melanoma (i.e., approval of KEYTRUDA®), recruitment has been slowed significantly.

"We are encouraged by these early safety and efficacy results and look forward to further data on GR-MD-02 used in combination with pembrolizumab in patients with metastatic melanoma or head and neck cancer," said Curti. "An objective response rate of five out of eight patients (62.5%) with advanced melanoma, including two complete responses, is very encouraging and compares favorably with the known response rates with pembrolizumab alone (ORR of ~ 33%). We have begun enrolling cohort 3 (GR-MD-02 8 mg/kg), which will include at least 10 patients with melanoma to provide a larger group of patients to evaluate. We hope to report additional data in mid-2018 when we anticipate a decision on progressing to phase 2. This decision will be based on the response rate of the combination with GR-MD-02 as compared to historical response rates to pembrolizumab alone."

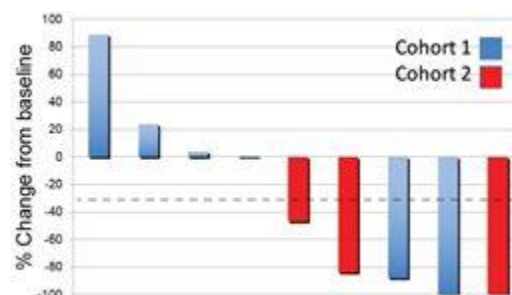
"Galectin Therapeutics is delighted with our collaboration and the excellent work by Providence Cancer Institute," said Peter Traber, M.D., CEO and CMO of Galectin Therapeutics. "It is known that galectin-3 produced by tumors is important in avoidance of immune recognition by cancer cells, and we are gratified by the large body of pre-clinical work and these early clinical trials that may support the combination of our galectin-3 inhibitor, GR-MD-02, with immune checkpoint inhibitors. It is important to note that not all galectin-3 inhibitors may be effective, as we have shown that a previous drug GM-CT-01 (DAVANAT®) had no effect in the same pre-clinical models. Finally, the use of combination immunotherapy with GR-MD-02 is covered by a joint Galectin-Providence U.S. patent with exclusive rights granted to Galectin."

About GR-MD-02

GR-MD-02 is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of fatty liver disease 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. The drug binds to galectin proteins and disrupts their function. Preclinical data in animals have shown that GR-MD-02 has robust treatment effects in reversing liver fibrosis and cirrhosis.

About Galectin Therapeutics

Galectin Therapeutics is developing promising carbohydrate-based therapies for the treatment of fibrotic liver disease and cancer based on the



Waterfall plot of best clinical response (RECIST 1.1) post-treatment. Dotted line at -30% change from baseline indicates the RECIST 1.1 threshold for definition of partial response.



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.

About Earle A. Chiles Research Institute, a division of Providence Cancer Institute, at the Robert W. Franz Cancer Center, in Portland, Ore.

Providence Cancer Institute, a part of Providence Health & Services, offers the latest in cancer services, including diagnostic, treatment, prevention, education, support and internationally-renowned research. The Earle A. Chiles Research Institute, a division of Providence Cancer Institute, is a world-class research facility located within the Robert W. Franz 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.chilesresearch.org.

Forwarding 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 Galectin 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 clinical trials will lead to the first therapy for the treatment of fatty liver disease with cirrhosis and those regarding the hope that Galectin's lead compounds will be successful in connection with cancer immunotherapy. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that 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; the Company's current clinical trial in fibrotic liver disease 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, 2016, 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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Source: Galectin Therapeutics Inc.

Source: Providence Cancer Institute