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## **Galectin Therapeutics and Providence Portland Medical Center Receive OK From FDA to Proceed With Phase 1B Clinical Trial in Metastatic Melanoma**

NORCROSS, Ga., Feb. 3, 2014 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today announced that the U.S. Food and Drug Administration (FDA) has agreed that a Phase 1B clinical trial of the galectin inhibitor GR-MD-02 in combination with Yervoy® (ipilimumab) in patients with metastatic melanoma may proceed. Providence Portland Medical Center, a leader in immunotherapy research and translational clinical trials in melanoma and other cancers, filed the IND in late December 2013.

Providence Portland Medical Center's Earle A. Chiles Research Institute (EACRI) will conduct the Phase 1B study under principal investigator Brendan D. Curti, M.D. The study will employ a 3+3 Phase 1 design with dose escalation of GR-MD-02 in conjunction with the standard therapeutic dose of ipilimumab in patients with advanced melanoma for whom ipilimumab would be considered standard of care. Researchers will assess the effects of GR-MD-02 with ipilimumab on melanoma response by inducing proliferation, activation and memory function of CD8+ T cells. In addition to monitoring for toxicity and clinical response, blood samples will be obtained to assess immunologic measures relevant to galectin biology and ipilimumab T-cell check-point inhibition.

"The FDA's IND agreement to proceed with the clinical trial is a critical step in seeking a new treatment option for metastatic melanoma, a devastating diagnosis for tens of thousands of Americans each year," said Dr. Peter G. Traber, President, Chief Executive Officer and Chief Medical Officer, Galectin Therapeutics. "We expect the trial to begin enrollment in March. Future communications will outline expected milestone timings for the study."

GR-MD-02 is Galectin Therapeutics' proprietary molecule that binds to and inhibits galectin proteins, predominantly galectin-3. A preclinical study led by tumor immunology expert William L. Redmond, Ph.D., of EACRI found that GR-MD-02 increased tumor shrinkage and enhanced survival in immune competent mice with prostate and breast cancers when combined with one of the immune checkpoint inhibitors, anti-CTLA-4 or anti-PD-1. These findings suggest a role for GR-MD-02 in cancer immunotherapy.

"Based on Dr. Redmond's work, we understand that GR-MD-02 potentially has an effect on tumor shrinkage, which could represent an important therapeutic approach," said Dr. Curti, the trial's principal investigator, a medical oncologist and director of the Providence Biotherapy Program at EACRI. "The Phase 1B trial of GR-MD-02 in combination with ipilimumab will sharpen our understanding of the effects of cancer immunotherapy on human disease."

Galectin Therapeutics will provide its proprietary compound GR-MD-02 to EACRI researchers, as well as 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 Company.

### **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 over 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, 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 Earle A. Chiles Research Institute at Providence Cancer Center is one of 10 research institutions selected to form the (BMS) International Immuno-Oncology Network. This global collaboration will focus on helping the body's own immune system fight cancer and bring more clinical trials to more patients in our community than ever before.

### **About Galectin Therapeutics**

Galectin Therapeutics (Nasdaq:GALT) 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, key mediators of biologic function. We are leveraging extensive scientific and development expertise as well as established relationships with external sources to achieve cost effective and efficient development. We are pursuing a clear development pathway to clinical enhancement and commercialization for our lead compounds in liver fibrosis and cancer. Additional information is available at [www.galectintherapeutics.com](http://www.galectintherapeutics.com).

## Forward Looking Statements

This press release contains, in addition to historical information, 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 our current expectations and are subject to factors and uncertainties which could cause actual results to differ materially from those described in the statements. These statements include those regarding preclinical data and the potential role for GR-MD-02 and GM-CT-01 in the treatment of liver fibrosis and cirrhosis and cancer in humans. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that our plans, expectations and goals regarding any preclinical data and potential therapeutic uses and benefits of our drugs and any future pre-clinical or clinical studies are subject to factors beyond our control. Future clinical studies may not begin or 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 our drugs are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies. Regardless of the results of current or future studies, we may be unsuccessful in developing partnerships with other companies or obtaining capital that would allow us to further develop and/or fund any studies or trials. To date, we have incurred operating losses since our inception, and our ability to successfully develop and market drugs may be impacted by our ability to manage costs and finance our continuing operations. For a discussion of additional factors impacting our business, see our Annual Report on Form 10-K for the year ended December 31, 2012, and our subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause our views to change, we disclaim any obligation to update forward-looking statements.

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