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Published Preclinical Study Demonstrates Therapeutic Effect of Galectin Inhibitors in Fatty Liver Disease With Fibrosis

NORCROSS, Ga., Dec. 19, 2013 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today announced that new preclinical data show its leading galectin-inhibiting drugs — GR-MD-02 and GM-CT-01 — demonstrate positive therapeutic effects on nonalcoholic steatohepatitis (NASH, or fatty liver disease) with fibrosis. Results were published in an article titled "Therapy of Experimental NASH and Fibrosis with Galectin Inhibitors" in the peer-reviewed, open-access journal *PLOS ONE*.

In the study, NASH-induced mice were treated with GM-CT-01 and GR-MD-02 at two different points — early fibrosis and later more severe fibrosis. The studies evaluated twice-weekly, dose escalation of once weekly by intravenous administration, as well as evaluated different routes of administration including intravenous, subcutaneous and oral.

Results revealed that treatment with GR-MD-02 significantly improved NASH activity and reduced fibrosis including prevention of accumulation of collagen and/or reduced accumulated collagen in the liver. Similar effects were seen with GM-CT-01 but with approximately four-fold lower potency than GR-MD-02. The data also show reduction in galectin-3 expression and other inflammatory biomarkers. The *PLOS ONE* article can be found online at http://dx.plos.org/10.1371/journal.pone.0083481

"There are currently no approved treatments for fatty liver disease with fibrosis, a major health problem in the United States. These preclinical findings add to our scientific understanding of the role galectin inhibitors play in the treatment of fatty liver disease," said Peter G. Traber, M.D., Chief Executive Officer, President and Chief Medical Officer, Galectin Therapeutics. "The results support our current Phase 1 clinical trial of GR-MD-02 and our long-term development programs for GM-CT-01 and GR-MD-02."

GM-CT-01 and GR-MD-02 are proprietary molecules that bind to and inhibit galectin proteins, predominantly galectin-3. Six of eight patients have been enrolled and infused in cohort 1 of a blinded Phase 1 clinical trial of GR-MD-02 for patients with NASH with advanced fibrosis. Enrollment continues and no serious adverse events have been reported. The Phase 1 first-in-man study is evaluating the safety, tolerability, pharmacokinetics and exploratory biomarkers for efficacy for single and multiple doses of GR-MD-02 when administered to patients with fatty liver disease with advanced fibrosis. Clinical data from the first cohort is expected early in 2014.

About Fatty Liver Disease with Advanced Fibrosis

Non-alcoholic steatohepatitis (NASH), also known as fatty liver disease, has become a common disease of the liver with the rise in obesity rates, estimated to affect nine to 15 million people, including children, in the U.S. Fatty liver disease is characterized by the presence of fat in the liver along with inflammation and damage in people who drink little or no alcohol. Over time, patients with fatty liver disease can develop fibrosis, or scarring of the liver, and it is estimated that as many as three million individuals will develop cirrhosis, a severe liver disease where liver transplantation is the only current treatment available. Approximately 6,300 liver transplants are done on an annual basis in the U.S. There are no drug therapies approved for the treatment of liver fibrosis.

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.

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 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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