



January 13, 2014

Galectin Therapeutics Announces Completion of Enrollment in First Cohort of Phase 1 Trial of GR-MD-02 in Fatty Liver Disease With Advanced Fibrosis

NORCROSS, Ga., Jan. 13, 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 patient enrollment in the first cohort of a Phase 1 trial of GR-MD-02 is now complete. The first-in-man study, which has successfully enrolled eight patients in the first cohort, is evaluating the safety, tolerability, and exploratory biomarkers for efficacy for single and multiple doses of GR-MD-02 when administered to patients with fatty liver disease (NASH) with advanced fibrosis. Intervention in NASH patients with advanced fibrosis, with the intent of reversing the fibrosis, is a potentially important therapeutic approach in this unmet medical need.

The Phase 1 multi-center, partially-blinded clinical trial will be conducted in a total of 24 patients who will receive four weekly doses of GR-MD-02. Each of the three cohorts consists of eight patients, six randomized to receive active drug and two randomized to receive placebo. The study is being conducted at six U.S. centers with extensive experience in clinical trials in liver disease. Two additional centers have been added to aid in the prompt enrollment of the next cohort.

"Completion of enrollment in the first cohort is an important step toward Galectin Therapeutics' objective of bringing a first-in-class treatment to the millions of Americans suffering from fatty liver disease with advanced fibrosis," said Dr. Peter G. Traber, President, Chief Executive Officer, and Chief Medical Officer of Galectin Therapeutics Inc. "To date, we have seen no serious adverse events in the trial. Following the 70 day study period and analysis of the data, we anticipate that initial safety and tolerability results, as well as biomarkers to evaluate for potential disease effect, from the first cohort will be available around the end of the first quarter of this year."

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 proteins play a major role in diseases that involve scarring of organs such as cancer, and inflammatory and fibrotic disorders. The drug binds to galectin proteins and disrupts their function. Preclinical data has shown that GR-MD-02 has robust treatment effects in reversing fibrosis and cirrhosis.

The trial is titled "A Multi-Center, Partially Blinded, Maximum Tolerated Multiple Dose Escalation, Phase 1 Clinical Trial to Evaluate the Safety of GR-MD-02 in Subjects with Non-Alcoholic Steatohepatitis (NASH) with Advanced Hepatic Fibrosis." Trial design details can be found at <http://clinicaltrials.gov/ct2/show/NCT01899859?term=gt-020&rank=1>.

In March 2013, the U.S. Food and Drug Administration (FDA) granted GR-MD-02 Fast Track designation for non-alcoholic steatohepatitis (NASH) with hepatic fibrosis, commonly known as fatty liver disease with advanced fibrosis.

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. FDA and AASLD (American Association for the Study of Liver Disease) recently held a 2-day workshop with leading scientific experts in NASH and key FDA officials to discuss acceptable regulatory endpoints for approval of drugs to treat NASH (<http://www.aasld.org/additionalmeetings/Pages/aasldfdanash.aspx>).

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 the anticipated timing of release of safety, tolerability and potential biomarker results among others. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, completion of the clinical trial protocols by the enrolled patients and processing of the resulting data. 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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