

First Cohort Results in Galectin Therapeutics' Phase 1 Trial Reveal Biomarker Evidence of Therapeutic Effect on Fibrosis and Inflammation in NASH With Advanced Fibrosis

- *GR-MD-02 was safe and well tolerated in patients*
- *Galectin Therapeutics to host webcast, April 1, 8:30 a.m. EDT to discuss first cohort findings*
- *Second cohort of Phase 1 trial to begin enrollment in April*

NORCROSS, Ga., March 31, 2014 (GLOBE NEWSWIRE) -- Galectin Therapeutics (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today announced that results from the first cohort of its Phase 1 trial show that GR-MD-02 had an effect on biomarkers that suggest a therapeutic effect on fibrosis, inflammation, and cellular injury. The first-in-man study, which enrolled eight patients in the first cohort, is evaluating the safety, tolerability, and exploratory biomarkers for efficacy for single and multiple doses of its galectin-inhibiting drug GR-MD-02 when administered to patients with fatty liver disease (NASH) with advanced fibrosis.

First cohort results indicate that GR-MD-02 was safe and well tolerated following four doses of 2 mg/kg (80 mg/m²) and there were no serious adverse events. The pharmacokinetics were consistent between individuals and after single and multiple doses with no drug accumulation after multiple doses. In assessing secondary endpoints, it was found that multiple biomarkers of fibrosis and inflammation showed improvement after four doses of GR-MD-02. Additionally, patients with greater evidence of liver cell injury, as indicated by elevated transaminase enzyme levels, had a marked decrease in CK-18, a clinically validated biomarker of cell death. Galectin-3 blood levels, which do not correlate with tissue levels in NASH, were not changed with treatment.

Details of the findings will be discussed by the Company on a webcast and conference call on Tuesday, April 1 at 8:30 a.m. Eastern Daylight Time. The webcast can be accessed at the following link: <http://w.on24.com/r.htm?e=773833&s=1&k=A95A6017BF0762550B5252D80F9A24FF>. Audio only can be accessed using the following call-in number: 866-219-3563, conference ID 19710441. The presentation is now posted on the Company's website (www.galectintherapeutics.com) for review before the webcast.

"We are extremely pleased with the positive results of the first cohort of our Phase 1 trial, which suggest a role for GR-MD-02 in the treatment of patients with fatty liver disease with advanced fibrosis," said Peter G. Traber, M.D., Chief Executive Officer, President and Chief Medical Officer of Galectin Therapeutics. "Fatty liver disease, characterized by the presence of fat in the liver along with inflammation, over time can develop into fibrosis, or scarring of the liver, which is estimated to affect millions of Americans. Intervention with the intent of reversing the fibrosis is a potentially important therapeutic approach in fatty liver disease, a condition with significant unmet medical need."

The Phase 1 multi-center, blinded (to healthcare providers and patients) clinical trial is being conducted in patients with NASH with advanced fibrosis (Brunt Stage 3) who receive four doses of GR-MD-02 over a 42-day period. Each of the three planned cohorts consists of eight patients, six randomized to receive active drug and two randomized to receive placebo. Eight U.S. clinical sites with extensive experience in clinical trials in liver disease are now active to facilitate rapid enrollment of the second cohort. Trial design details can be found at <http://clinicaltrials.gov/ct2/show/NCT01899859?term=gt-020&rank=1>.

The second cohort, which will begin enrollment in April, will include an increased dose of GR-MD-02 to 4 mg/kg (160 mg/m²). FibroScan™, an ultrasonic measure of liver tissue elasticity approved by the U.S. Food and Drug Administration, was added to the trial's protocol to provide another assessment of liver fibrosis. For those sites with access to FibroScan™, measurements will be performed at baseline and after the four doses. It is estimated results from the second cohort will be reported in late summer 2014.

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 has shown that GR-MD-02 has robust treatment effects in reversing liver fibrosis and cirrhosis.

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 the clinical trial, including the expected timing of results for the second cohort, and potential benefits and therapeutic effects of GR-MD-02. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that we may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of GR-MD-02 or any of our other drugs in development. Our current clinical trial and any future clinical studies may not produce positive results in a timely fashion, if at all, and could prove time consuming and costly. We may have difficulty enrolling new patients, which could impact timing and costs. Results from the first cohort of Phase 1 are not necessarily indicative of future results in the clinical trial. 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 any of our development programs, we may be unsuccessful in developing partnerships with other companies 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, 2013, 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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