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Galectin Therapeutics Announces First Patient Dosed in Second Cohort of Phase 1 Trial of GR-MD-02 for NASH With Advanced Fibrosis

NORCROSS, Ga., April 17, 2014 (GLOBE NEWSWIRE) -- Galectin Therapeutics (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announced today that the first patient in cohort 2 of its Phase 1 clinical trial of GR-MD-02 in patients with NASH with advanced fibrosis has been successfully dosed with 4 mg/kg, which is double the dose given in cohort 1. Cohort 2, as with all phases of the clinical trial, was initiated in full compliance with the rules, regulations, and specific conditions set forth by the U.S. Food and Drug Administration (FDA) for this Phase 1 clinical trial. The second cohort follows highly successful results from the first cohort showing that 2 mg/kg was safe and very well tolerated, and that GR-MD-02 treatment resulted in significant improvement in multiple biomarkers of fibrosis and liver inflammation in patients with NASH with advanced fibrosis (see full results: http://galectintherapeutics.com/wp-content/uploads/2014/03/20140401GT020FirstCohortFINAL.pdf). The remaining patients in cohort 2 are expected to be enrolled over the next few weeks and we anticipate reporting the results of cohort 2 around the end of July.

"We were extremely pleased with the results of the first cohort, which demonstrated significant biomarker effects on fibrosis and inflammation in all the patients treated with GR-MD-02, coupled with good safety and tolerability," said Dr. Peter G. Traber, President, Chief Executive Officer, and Chief Medical Officer of Galectin Therapeutics Inc. "These positive results have propelled the enrollment of the second cohort with strong participation across our clinical trial sites. We anticipate the cohort 2 results will further support the use of GR-MD-02 in patients with NASH and advanced fibrosis, with the goal of reversing fibrosis and preventing complications of cirrhosis and liver transplantation."

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 2013, Galectin Therapeutics received Fast Track designation from the FDA for this clinical development program. FDA grants Fast Track designation to help expedite review and approval of drugs in development that treat serious or life threatening diseases and fill an unmet medical need.

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," "anticipated," "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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