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# Clinical Trial Sites for First Human Clinical Trial for Treatment of Fatty Liver Disease with Advanced Fibrosis Announced by Galectin Therapeutics

NORCROSS, Ga., April 9, 2013 /PRNewswire/ -- Galectin Therapeutics (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announced details today on its first-in-man Phase 1 clinical trial that will support a proposed indication of GR-MD-02 for treatment of non-alcoholic steatohepatitis (NASH, or fatty liver disease) with advanced fibrosis. The Phase 1 Clinical Trial is entitled, "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" and will be conducted in six centers in the United States which have extensive experience in conducting clinical trials in liver disease.

"We are delighted to have recruited world class US investigators in NASH to conduct this initial study in our development program to treat liver fibrosis associated with fatty liver," said Dr. Peter G. Traber, President, Chief Executive Officer, and Chief Medical Officer of Galectin Therapeutics Inc. "The clinical trial will be conducted in patients with NASH and advanced fibrosis who will receive four weekly doses of GR-MD-02 and, while evaluation for safety is the primary objective, a series of biomarkers will be evaluated to assess for early signs of efficacy. Therefore, we anticipate obtaining more data from this study than the typical Phase 1 clinical trial."

The clinical trial investigator kick-off meeting was held in Atlanta GA on April 5 2013, led by Galectin and CTI Clinical Trials & Consulting Services Inc of Cincinnati Ohio, a full service clinical research organization with extensive experience in liver-related clinical trials. The investigators and sites that will conduct the study include: Dr. Stephen Harrison of the Brooke Army Medical Center at Fort Sam Houston in San Antonio TX, Dr. Naga Chalasani of Indiana University School of Medicine in Indianapolis IN, Dr. Brent Tetri of St. Louis University School of Medicine in St. Louis MO, Dr. Arun Sanyal of Virginia Commonwealth University School of Medicine in Richmond VA, Dr. Ram Subramanian of Emory University School of Medicine in Atlanta GA, and Dr. Thomas Schiano of Icahn School of Medicine at Mount Sinai in New York City. It is anticipated that the enrollment and infusion of the first cohort will be completed by the end of Q2 2013.

The study is planned to enroll the first cohort followed by potential sequential cohorts receiving increasing doses of GR-MD-02 with eight patients in each cohort randomized 6:2 (study drug:placebo); the patients and medical staff will be blinded to whether the patient is receiving drug or placebo. After the safety of the first dose is assessed, the patients will receive three additional doses weekly doses of GR-MD-02. The dose will be increased after assessment of each cohort to presumptive target therapeutic levels which is currently projected to take one year from the start of the study. In addition to patient safety and GR-MD-02 pharmacokinetics, each patient will have assessment of over two dozen biomarkers of NASH and fibrosis to evaluate for an early indication of drug effect.

**About NASH**

NASH has become a common disease of the liver with the rise in obesity rates, affecting 9 to 15 million people, including children, in the United States. NASH 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 NASH can develop fibrosis, or scarring of the liver, and it is estimated that as many as 3,000,000 will develop cirrhosis, a severe liver disease where transplantation is the only current treatment available. Approximately 6,300 liver transplants are done on an annual basis in the United States. There are currently not approved medical therapies for NASH or fibrosis of the liver.

**About Galectin Therapeutics Inc.**

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, statements that look forward in time or that express management's beliefs, expectations or hopes. Such statements are 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 risks and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include our plans, expectations and goals regarding the clinical trial and estimates regarding those impacted by NASH. Our plans, expectations and goals regarding the clinical trial are subject to factors beyond our control. Our clinical trial may not begin or produce positive results in a timely fashion, if at all, and any necessary changes during the course of the trial could prove time consuming and costly. We may have difficulty in enrolling candidates for testing and we may not be able to achieve the desired results. Upon receipt of FDA approval, we may face competition with other drugs and treatments that are currently approved or those that are currently in development, which could have an adverse impact on our ability to achieve revenues from this proposed indication. Plans regarding development, approval and marketing of any of our drugs, including GR-MD-02, are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies. 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.

SOURCE Galectin Therapeutics Inc.

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