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Galectin Therapeutics Announces First Patient Dosed in Phase 1 Trial of GR-MD-02, a Potential First-in-Class Treatment for Fatty Liver Disease with Advanced Fibrosis

NORCROSS, Ga., July 24, 2013 /PRNewswire-USNewswire/ -- Galectin Therapeutics (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announced today that the first patient has been successfully dosed in a Phase 1 clinical trial of GR-MD-02. The first-in-man study will evaluate 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 with advanced fibrosis.

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 scaring 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 successful first patient dosing in the clinical trial of GR-MD-02 is a critical milestone in Galectin's development program. There are currently no treatments for fatty liver disease with advanced fibrosis; this milestone takes us one step closer to bringing a first-in-class treatment to the millions of Americans suffering from this silent epidemic," said Dr. Peter G. Traber, President, Chief Executive Officer, and Chief Medical Officer of Galectin Therapeutics Inc. "We anticipate that enrollment of the first cohort of eight patients in the Phase 1 trial will be complete by late summer with initial safety and tolerability results available following the 70 day study period and analysis of the data."

The Phase 1 multi-center, partially-blinded clinical trial will be conducted in 24 patients with fatty liver disease and advanced fibrosis who will receive four weekly doses of GR-MD-02. The study, which includes a dose escalation design, will be conducted at six US centers with extensive experience in clinical trials in liver disease. This first patient dosing took place at Indiana University under the direction of the Principal Investigator Dr. Naga Chalasani, a world-renowned expert in NASH.

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.

An estimated 9 to 15 million Americans, including children, are affected by fatty liver disease. Without an available therapeutic treatment, the only alternative for patients with fatty liver disease is a transplant but there are limited donors available and the procedure is costly.

Recently, Galectin submitted a Fast Track application to the FDA to help expedite its clinical development program of GR-MD-02 in fatty liver disease with advanced fibrosis. 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 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.

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. Follow us on Twitter @GalectinGALT.

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 those regarding our plans, expectations and goals regarding the clinical trial, our

Fast Track submission and the potential benefits of a Fast Track designation, and our estimates regarding those impacted by NASH. 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 the clinical trial are subject to factors beyond our control. Our clinical trial may not 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. Also, receipt of a Fast Track designation from the FDA is beyond our control and the FDA may not approve our application. In regard to our clinical trial, we may have difficulty in enrolling candidates for testing, which would impact our estimates regarding timing, 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