June 29, 2015

Galectin Therapeutics Initiates Enrollment for GR-MD-02 Phase 2 Clinical Trial in NASH with Cirrhosis

First Five Patients Screened

NORCROSS, Ga., June 29, 2015 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (NASDAQ:GALT), a leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today announced the screening of the first five patients in its Phase 2 clinical trial with GR-MD-02 in nonalcoholic steatohepatitis (NASH) with cirrhosis. This study, the NASH-CX trial, is a multicenter, randomized, placebo-controlled, double-blind, parallel-group Phase 2 trial to evaluate the safety and efficacy of GR-MD-02 for the treatment of liver fibrosis and resultant portal hypertension in patients with NASH cirrhosis.

Co-lead investigators are Stephen A. Harrison, M.D., FACP, Colonel, Medical Corps U.S.A., Director, Medical Education, Associate Dean, San Antonio Uniformed Services Health Education Consortium, Professor of Medicine, Uniformed Services University of the Health Sciences Consultant to The Surgeon General for Gastroenterological Diseases, Brooke Army Medical Center /San Antonio Military Medical Center; and, Naga Chalasani, MD, FACG, David W. Crabb Professor & Director, Division of Gastroenterology and Hepatology, Indiana University School of Medicine.

"We are very excited that patient screening has begun in our NASH-CX Phase 2 study, the larger of the two trials comprising our Phase 2 program," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. "We are delighted that Drs. Harrison and Chalasani have agreed to serve as co-lead investigators, as they are important thought leaders in field of NASH. Indeed Dr. Harrison is an associate editor for *Hepatology,* the official journal of the American Association for the Study of Liver Diseases, and Dr. Chalasani has well over 100 published papers on NASH and other diseases of the liver."

"We have worked diligently along with PPD, our contract research organization, to advance to this point in our development. PPD has extensive experience in conducting clinical trials in NASH and cirrhosis, and we are very pleased with the pace of site recruitment. In addition, these sites have experience with measuring hepatic venous pressure gradient (HVPG), our primary endpoint, which is reflective of clinical outcomes in cirrhosis. We will correlate HVPG with liver biopsy as a secondary endpoint both at the beginning and the completion of the 52-week treatment period. In addition, non-invasive tests as secondary endpoints will be conducted at the beginning, middle and end of the study."

Dr. Traber continued, "Our preclinical research shows that GR-MD-02 binds to Galectin-3, a well-validated target, and our work in preclinical models suggests that GR-MD-02 reverses liver fibrosis and cirrhosis. As a result of the preclinical observations in disease that we noted, we are concentrating our Phase 2 study in the most ill patients - Stage 4 on the NASH spectrum -as these patients have an increased mortality.

"Our two completed Phase 1 trials provide a strong foundation for our NASH Phase 2 program. In a multiple dose-escalation, double-blind, placebo-controlled trial, we found GR-MD-02 to be safe and well tolerated, and noted that the highest dose, 8 mg/kg, may have had an effect on fibrosis as shown by reduced serum alpha-2 macroglobulin, a marker of fibrosis, and reduced liver stiffness as assessed by FibroScan®. In addition, in a drug-drug interaction study between GR-MD-02 and midazolam, a commonly used sedative, there was no interaction, suggesting an additional layer of safety," Dr. Traber added.

Dr. Traber continued, "The commercial potential of a drug that treats late stage fibrosis and cirrhosis should be excellent. While many other companies are investigating therapeutics in early, low stage fibrosis NASH, we believe that the sense of urgency for treatment by physicians, patients and payors will be less robust than that of late stage NASH with its heightened mortality. In fact, the scope of this disease is such that by 2025 the worldwide market for NASH treatments could approach $35 billion, according to a recent biotech analyst report," he concluded.

About the NASH-CX Study

A total of 156 patients at between 45 and 60 sites will be randomized to receive either 2 mg/kg of GR-MD-02, 8 mg/kg of GR-MD-02 or placebo, with 52 patients in each arm. The primary endpoint is a reduction in HVPG. Patients will receive a total of 26 infusions every other week for one year and will be evaluated to determine the change in HVPG as compared with placebo. HVPG will be correlated with secondary endpoints of fibrosis on liver biopsy as well as with measurement of liver stiffness (FibroScan®) and assessment of liver metabolism (^{13}C-methacetin breath test, Exalenz), which are non-invasive measures of the liver that may be used in future studies. Data readout is expected in the fourth quarter of 2017. More information may be found at www.clinicaltrials.gov.

About the NASH-FX Study

The Company also expects to begin screening patients with advanced fibrosis (the NASH-FX trial) in a smaller, 30 patient study in August 2015, with 15 patients receiving 8 mg/kg of GR-MD-02 and 15 receiving placebo. That study will evaluate the safety and efficacy of GR-MD-02 on liver stiffness as assessed by magnetic resonance-elastography and FibroScan score, and on imaging of liver fibrosis using multi-parametric magnetic resonance imaging (LiverMultiScan®, Perspectum Diagnostics). Top-line data is expected to be available in mid-2016. More information may be found at www.clinicaltrials.gov.

About GR-MD-02

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

About Fatty Liver Disease with Advanced Fibrosis and Cirrhosis

Non-alcoholic steatohepatitis (NASH), also known as fatty liver disease, has become a common disease of the liver with the rise in obesity rates. NASH is estimated to affect up to 28 million people 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 consume 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 1-2 million individuals in the U.S. will develop cirrhosis, a severe liver disease for which liver transplantation is the only treatment available. Approximately 6,300 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis.

About Galectin Therapeutics

Galectin Therapeutics 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, which are key mediators of biologic function. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. The Company is pursuing a development pathway to clinical enhancement and commercialization for its lead compounds in liver fibrosis and cancer. Additional information is available at www.galectintherapeutics.com.

Forward Looking Statements

This press release contains 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 management's current expectations and are subject to factors and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include those regarding the hope that Galectin's development program for GR-MD-02 will lead to the first therapy for the treatment of fatty liver disease with cirrhosis. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of GR-MD-02 or any of its other drugs in development. The Company's 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. Plans regarding development, approval and marketing of any of Galectin's drugs are subject to change at any time based on the changing needs of the Company as determined by management and regulatory agencies. Carbohydrates are a relatively new drug class, and regulatory requirements are evolving; we cannot assure that will be able to meet such requirements in a timely and cost effective manner in the manufacturing and characterization of our products. Regardless of the results of any of its development programs, Galectin may be unsuccessful in developing partnerships with other companies or raising additional capital that would allow it to further develop and/or fund any studies or trials. Galectin has incurred operating losses since inception, and its ability to successfully develop and market drugs may be impacted by its ability to manage costs and finance continuing operations. For a discussion of additional factors impacting Galectin's business, see the Company's Annual Report on Form 10-K for the year ended December 31, 2014, and subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

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Source: Galectin Therapeutics, Inc.

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