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Galectin Therapeutics Announces Start of Phase 2 Clinical Trial With GR-MD-02 in NASH With Advanced Fibrosis

Second Trial in GR-MD-02 Phase 2 Program Features Non-Invasive Endpoints and Shorter Treatment Duration; Data Readout Expected in the Third Quarter of 2016

NORCROSS, Ga., Sept. 16, 2015 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announces the commencement of its Phase 2 clinical trial with GR-MD-02 in patients with non-alcoholic steatohepatitis (NASH) with advanced fibrosis (the NASH-FX trial). This 30-patient study is being conducted by Stephen A. Harrison, M.D., FACP, FAASLD, 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 and Consultant to The Army Surgeon General for Gastroenterological Diseases, San Antonio Military Medical Center. The NASH-FX trial, which focuses on advanced fibrosis, is part of Galectin's overall Phase 2 clinical program with GR-MD-02 in NASH that addresses both advanced fibrosis and cirrhosis.

The NASH-FX trial will enroll 15 NASH patients with advanced fibrosis (stage 3) to receive 8 mg/kg of GR-MD-02 and 15 to receive placebo every other week for 16 weeks, for a total of nine doses. Following the treatment period, the effect of GR-MD-02 on liver fibrosis will be assessed by three independent non-invasive tests. The primary endpoint will be an assessment of fibrosis using multi-parametric magnetic resonance imaging (LiverMultiScan®), which is a validated and proprietary MRI protocol developed by Perspectum Diagnostics. Secondary endpoints will evaluate liver stiffness, which correlates to the degree of liver fibrosis, as assessed by magnetic resonance-elastography and FibroScan®. Top-line data is expected to be available in the third quarter of 2016.

"We are delighted to commence the second part of our Phase 2 clinical program with GR-MD-02 in NASH with advanced fibrosis and cirrhosis," said Peter G. Traber, M.D., Galectin's president, chief executive officer and chief medical officer. "Importantly, the NASH-FX trial will employ non-invasive measures as surrogates for NASH with advanced fibrosis. While the goal of this study is to determine the safety and efficacy of GR-MD-02, we also expect this trial to provide important information about the non-invasive diagnostic methods that may be utilized in subsequent studies."

More information on the NASH-FX trial may be found in a recent post on Dr. Traber's blog, *CEO Perspectives* and at www.clinicaltrials.gov.

Commenting on the study, Dr. Harrison said, "NASH is a silent killer of far too many as patients remain asymptomatic, often for many years, until the disease has progressed to advanced fibrosis and cirrhosis. I am very excited to be involved with Galectin's clinical trial program as we work toward finding a compound that might reverse the damage caused by this disease."

The NASH-CX trial is testing two dose levels of GR-MD-02 (8 mg/kg and 2 mg/kg) and will ultimately enroll 156 patients with NASH with cirrhosis who will undergo liver biopsy at the beginning and end of a 52-week treatment period for a total of 26 doses. Patient screening in the NASH-CX trial began in June 2015 and top-line data readout is expected in late 2017. Dr. Harrison also is a lead investigator in the NASH-CX study.

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. have cirrhosis, a severe liver disease for which liver transplant 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 NASH or liver fibrosis. A recent analyst estimate indicated that by 2025 the worldwide market for NASH treatments could approach $35 billion.

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. With the size of the NASH-FX trial and its reliance on non-invasive testing the data obtained from the trial may not be predictive of future results, may be negative or inconclusive and are susceptible to varying interpretations. Relying on one medical center, enrollment could be delayed, thus extending the time period during which top line results may become available. 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 trials 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; and 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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