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Galectin Therapeutics Announces Complete Enrollment in its Phase 2 Trial with GR-MD-02 in NASH Patients with Advanced Fibrosis

Top line results of the NASH-FX trial to be reported in September 2016

NORCROSS, Ga., May 11, 2016 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announces the completion of enrollment in its Phase 2 clinical trial with GR-MD-02 in patients with non-alcoholic steatohepatitis (NASH) with advanced fibrosis (stage 3) (the NASH-FX trial). The Company expects to report the top line results of this trial by the end of September 2016, as previously planned.

"We are pleased that enrollment in our NASH-FX trial was completed right on schedule," said Peter G. Traber, M.D., Galectin's president, chief executive officer and chief medical officer. "This is one of two Phase 2 trials we are conducting in subjects with NASH, and is designed to assess the efficacy of our lead compound GR-MD-02 in patients with NASH with advanced fibrosis (stage 3). Since the diagnosis of NASH and the monitoring of the disease are hampered by the need for liver biopsy, in addition to providing proof-of-concept on the efficacy of GR-MD-02, this study explores the utility of three non-invasive measures of fibrosis which may be useful in the design and execution of later stage clinical studies and perhaps have relevance in commercial clinical settings."

The NASH-FX trial has enrolled a total of 30 liver biopsy-confirmed NASH patients with advanced fibrosis (stage 3) - 15 patients to receive 8 mg/kg of GR-MD-02 and 15 patients to receive placebo every other week for 16 weeks, for a total of nine doses. The effect of GR-MD-02 on liver fibrosis will be assessed by three independent non-invasive tests following the treatment period. 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 by FibroScan®. More information on the NASH-FX trial may be found in a post on Dr. Traber's blog, CEO Perspectives and at www.clinicaltrials.gov.

This single-site 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. Dr. Harrison is also the co-lead investigator for Galectin's Phase 2 NASH-CX trial, which is studying two different doses of GR-MD-02 against placebo in 156 patients with NASH with cirrhosis (the NASH-CX trial).

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. 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 advanced fibrosis and/or cirrhosis and/or moderate to severe psoriasis. 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. 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, 2015, 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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