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Galectin Therapeutics Announces Completion of Patient Recruitment in its Phase 2 Trial with GR-MD-02 in NASH Patients with Cirrhosis

NORCROSS, Ga., Aug. 02, 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 patient recruitment in its Phase 2 clinical trial with GR-MD-02 in patients with non-alcoholic steatohepatitis (NASH) with cirrhosis (the NASH-CX trial). The Company expects to report the topline results of this trial in December 2017, as previously planned.

"We are pleased that patient recruitment in our NASH-CX trial was completed ahead of our original expectations," 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 it is designed to assess the efficacy of our lead compound GR-MD-02 in patients with NASH cirrhosis. This trial was designed and is being conducted with a primary endpoint that the U.S. Food and Drug Administration views may be a surrogate for outcomes for registration trials in this patient population."

The NASH-CX trial has recruited and consented 290 patients, with the goal to enter 156 liver biopsy-confirmed NASH cirrhosis patients into the treatment phase. Patients are required to meet major screening criteria before starting the treatment phase of the trial including a hepatic venous pressure gradient (HVPG) > = 6 mm Hg, confirmation of NASH fibrosis stage by biopsy (Brunt fibrosis stage 4, modified Ishak fibrosis stage 5 or 6), amongst other criteria. The screening period from recruitment to initiating treatment is approximately 8 weeks and the screen fail rate is approximately 40 percent of patients recruited, as per the original study plan. Therefore, the study should meet its full complement of treated patients to meet the previously stated goal of topline data readout in December 2017.

Enrolled patients are receiving either 8 mg/kg or 2 mg/kg of GR-MD-02 or placebo every other week for 52 weeks, for a total of 26 doses. The primary study endpoint is a reduction in HVPG. Patients treated with GR-MD-02 will be evaluated to determine the change in HVPG as compared to patients treated with placebo. HVPG will be correlated with secondary endpoints of liver biopsy fibrosis staging, measurement of liver stiffness (FibroScan$^{(R)}$), 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. More information on the NASH-CX trial may be found in a post on Dr. Traber's blog, *CEO Perspectives* and at www.clinicaltrials.gov.

"NASH cirrhosis, and indeed all etiologies of cirrhosis, represent a large unmet medical need with no currently approved medical therapies," said Dr. Traber. "A drug that can halt progression of, or reverse existing fibrosis, in NASH cirrhosis patients would be a welcome therapeutic intervention that may prevent complications, alleviate the need for liver transplant, and prevent death. While progression to cirrhosis in NASH is not common, the enormous number of people with fatty liver disease globally suggests that nearly 20 million people currently with fatty liver disease across the world may die of their disease. Read more about the global scope of this problem in my recent *CEO Perspective*."

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 scarring 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 fatty liver disease (NAFLD) has become the most common disease of the liver, generally associated with the rise in obesity rates. NAFLD is characterized by the presence of fat in the liver in people who consume little or no alcohol, and when associated with inflammation and cell damage is called non-alcoholic steatohepatitis (NASH). Over time, patients with NASH can develop fibrosis, or scarring of the liver, which may progress to severe fibrosis, called cirrhosis. Approximately one in four people in the world have NAFLD, with 5% of those developing cirrhosis, and 2% eventually dying of the disease. These data translate into ~20,000,000 liver-related deaths among patients currently alive with NAFLD. There are no drug therapies approved for the treatment of NASH, liver fibrosis, or cirrhosis, for which liver transplant is the only treatment available. 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 . 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 complete its ongoing or subsequent 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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