September 27, 2016

Galectin Therapeutics Announces Top-Line Data from Exploratory Phase 2a Pilot Trial (NASH-FX) with GR-MD-02 in NASH Patients with Advanced Fibrosis

Larger Phase 2b clinical trial in NASH cirrhosis (NASH-CX) now completely enrolled

Closed private placement financing for $1.5 million

Conference call to be held today at 5:30 p.m. (Eastern Time)

NORCOSS, Ga., Sept. 27, 2016 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today announced topline results from NASH-FX, its Phase 2a clinical trial evaluating the efficacy, safety, and tolerability of GR-MD-02 in 30 nonalcoholic steatohepatitis (NASH) patients with advanced fibrosis. This exploratory, single site, short-treatment (four months of therapy), randomized study did not meet its primary biomarker endpoint as measured by LiverMultiScan (LMS, Perspectum Diagnostics), a magnetic resonance imaging test that evaluates inflammation and fibrosis. The trial also did not meet secondary endpoints that measure liver stiffness as a surrogate for fibrosis, with FibroScan® and magnetic resonance elastography (MRE). While all patients had a baseline liver biopsy to establish the diagnosis and fibrosis severity, liver biopsies were not performed at the end of the study following treatment due to safety considerations involved with liver biopsy-related risk in a short duration trial. GR-MD-02 was found to be safe and well tolerated among the patient population with no serious adverse events.

Importantly, Galectin simultaneously announced that the principal focus of its research efforts—its larger scale, one-year, multi-site trial in patients with NASH cirrhosis (NASH-CX)—has completed enrollment one month early with 162 total subjects (exceeding the target of 156 patients), allowing for reporting of top-line results in December 2017. In further contrast to the NASH-FX trial, the NASH-CX trial is being conducted with a primary endpoint (hepatic venous pressure gradient (HVPG)) which the U.S. Food and Drug Administration may view as an acceptable surrogate for outcomes for registration trials in this patient population.

"Although there was no apparent improvement in the three non-invasive tests for assessment of liver fibrosis in this four month pilot trial, inhibition of galectin-3 with GR-MD-02 remains promising for treatment of NASH fibrosis," said Stephen A. Harrison, M.D., the principal investigator (PI) of the NASH-FX trial, medical director of Pinnacle Clinical Research in San Antonio, TX, and visiting professor of medicine at the University of Oxford, UK. "In regard to the potential activity of GR-MD-02, it is encouraging that there is an important clinical effect in moderate-to-severe psoriasis, suggesting the compound has activity in a human disease that can occur in association with NASH."

Dr. Harrison, who is also the co-lead PI of the NASH-CX trial, continued, "The NASH-FX trial was designed to follow up on limited data from a Phase 1 study in NASH with advanced fibrosis, which suggested that FibroScan® measurements may have improved with just four doses of drug. However, as we have witnessed in other liver fibrosis trials, the relatively short treatment duration of only four months assessed in the NASH-FX was inadequate to see an efficacy response. Therefore, we look forward to additional results from the NASH-CX trial in which patients with NASH cirrhosis are treated for one year."

Naga Chalasani, M.D., the other co-lead PI of the NASH-CX trial and chief of the Division of Gastroenterology and Hepatology at Indiana University, said, "In my assessment, the results from the NASH-FX trial do not diminish the significance of the NASH-CX trial. Along with the safety and tolerability profile observed in the NASH-FX trial, the different patient population, much larger enrollment, rigorous study design and longer duration of therapy offer compelling rationale to complete the NASH-CX trial."

With over 1,600 drug doses administered there is now substantial clinical trial experience with GR-MD-02. There is no evidence of serious adverse effects related to the drug, highlighting the good safety profile of the therapy in this patient population with advanced stage disease. In the NASH-CX trial 64 patients have already completed 6 months of dosing with a low drop-out rate of only 3 patients prematurely exiting the trial.

In support for continued funding of the NASH-CX trial, a private placement financing for $1.5 million from a single source was signed on September 22, 2016. "It is encouraging that we have the confidence of a highly-respected businessman such as Mr. Richard Uihlein, who has now invested $1.5 million in Galectin through a limited partnership investment fund, which adds to his current significant stake in the company," added Peter Traber, M.D., Galectin's president, chief executive officer and chief medical officer. "Mr. Uihlein is further committed to helping the company progress through the completion of the NASH-

CX trial. We will continue to pursue the additional funding required to support our clinical development program."

Conference Call Information
Galectin will hold a conference call today at 5:30 p.m. Eastern Time to provide an update by Dr. Peter Traber and Dr. Stephen Harrison on the progress of its lead development program.

Date: September 27, 2016
Time: 5:30 p.m. Eastern Time
Toll-Free: 1-888-317-6003
Passcode: 4681161
Webcast: http://services.choruscall.com/links/galt160927.html

The full transcript of the conference call can be accessed on the Investor Relations page of Galectin's website, http://investor.galectintherapeutics.com/, approximately 24 hours after the completion of the call, and will be available for 60 days following the call.

About NASH-CX Trial
Galectin announced in August the completion of patient recruitment ahead of original expectations in the NASH-CX trial, its Phase 2b clinical trial with GR-MD-02 in patients with NASH with cirrhosis. The Company has enrolled 162 liver biopsy-confirmed NASH cirrhosis patents into the treatment phase, with the original goal to enter 156 patients. 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 of hepatic venous pressure gradient (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 at baseline and the end of the trial, measurement of liver stiffness (FibroScan®), and assessment of liver metabolism (^{13}C-methacetin breath test, Exalenz). The Company projects topline results of this trial will be available in December 2017. 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.

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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