January 7, 2015

Final Phase 1 Trial Results Demonstrate Galectin Therapeutics' GR-MD-02 is Safe With Potential for Therapeutic Effect on Fibrosis in NASH Patients With Advanced Fibrosis

NORCROSS, Ga., Jan. 7, 2015 (GLOBE NEWSWIRE) -- Galectin Therapeutics (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announces that final results from its Phase 1 trial show that GR-MD-02 had an effect on a serum biomarker (as assessed by FibroTest®) and liver stiffness (as assessed by FibroScan®) that suggest a potential for therapeutic effect on fibrosis that warrants further exploration. This first-in-man study, which enrolled 30 patients in three cohorts, principally evaluated the safety, tolerability and pharmacokinetics for single and multiple doses of its galectin-inhibiting drug GR-MD-02 when administered intravenously to patients with fatty liver disease, or nonalcoholic steatohepatitis (NASH) with advanced fibrosis. The study also secondarily examined exploratory biomarkers as well as a newer non-invasive liver stiffness measure. Final Phase 1 data are included in a new corporate presentation which is available on the Company's website (www.galectintherapeutics.com).

GR-MD-02 administered to patients in three cohorts in doses up to 8 mg/kg for a total of four doses was found to be safe and well-tolerated. There were no serious adverse events or treatment-emergent adverse events attributed to the study drug. Mild (grade 1) adverse events possibly attributable to drug were identified in more patients receiving placebo (4 patients) than those receiving active drug (2 patients). The pharmacokinetic analysis of GR-MD-02 plasma levels for the 8 mg/kg dose shows that plasma drug coverage was in the upper portion of the targeted therapeutic range derived from NASH animal model studies. Therefore, the highest dose in the third cohort suggested a desired dose for testing in Phase 2 clinical trials.

"The final conclusion of the Phase 1 trial is that GR-MD-02 is safe and well tolerated after multiple doses," said Stephen A. Harrison, M.D., the lead investigator of the trial and Chief of Hepatology at Brooke Army Medical Center in Fort Sam Houston. "Additionally, the highest dose utilized is within the therapeutic range, and had significant effects on a relevant biomarker of fibrotic liver disease and a potential signal indicating a reduction in liver stiffness. These findings provide a firm foundation for a Phase 2 clinical trial program and I am enthusiastic about participating in these trials." Dr. Harrison also presented interim results of the study at the 2014 AASLD annual meeting, where he represented a group of principal investigators from leading medical institutions in the U.S., many of whom have authored seminal publications on liver disease and NASH in particular.

Evaluation of FibroTest®, a biomarker consisting of a composite score of five blood tests that correlates with the extent of liver fibrosis, showed a statistically significant reduction between patients administered 8 mg/kg GR-MD-02 and those administered placebo in cohort 3. In contrast, there was no evidence of a significant reduction with the doses administered in the first two cohorts (2 mg/kg and 4 mg/kg), thereby suggesting a dose-dependent pharmacodynamic effect of GR-MD-02, which will be further explored in Phase 2 studies. The decrease in FibroTest® score was attributable to a marked, statistically significant reduction in serum alpha-2 macroglobulin (A2M), a component of the FibroTest® score and a serum protein that has been associated with liver fibrosis. A2M is a relevant marker for liver fibrosis because it has been shown that serum levels correlate with liver fibrosis. Moreover, it may be involved in the pathogenesis of fibrosis because it is known to inhibit proteases such as collagenase, which may promote fibrosis, and is increased in fibrogenic stellate cells in liver fibrosis.

Patients in the third cohort were also evaluated for liver stiffness with FibroScan®, an ultrasound-based instrument approved by the U.S. Food and Drug Administration (FDA) for use in non-invasive liver diagnosis. Liver stiffness as measured by FibroScan® has been shown in multiple studies to correlate with the degree of liver fibrosis as assessed by liver biopsy. The area of the liver interrogated with this method is approximately 100-times larger than the size of a standard liver biopsy. Although not cleared by the FDA specifically to assess fibrosis, FibroScan® is believed to represent a promising non-invasive, out-patient method for measuring changes in liver fibrosis over time without the need for invasive surgical liver biopsy.

While FibroScan® analysis was added during cohort 2, too few scans were obtained among those patients for analysis. In cohort 3 there were technically adequate scans at baseline, Day 38 and Day 63 in 5 patients administered GR-MD-02 and 3 patients administered placebo. Five patients in cohort 3 were not available for FibroScan® analysis (3 placebo and 2 active) because of unavailability of the instrument at the site (1 placebo and 1 active), unavailability of the appropriate instrument probe (1 active), a technically inadequate baseline scan (1 placebo) and the Day 63 scan not being performed (1 placebo). All 3 placebo patients showed no significant change in FibroScan® scores from baseline to Day 63, defined as changes of ±20% from baseline. In contrast, 3 of the 5 patients administered GR-MD-02 showed a reduction in FibroScan ® scores at Day 63 with reductions of 25%, 49% and 53%. While the number of patients in this analysis is small, these findings suggest there may be a reduction in liver stiffness with GR-MD-02 in some patients, which may correlate with the state of fibrosis and warrants that these observations be further explored in Phase 2 studies.

"We are pleased that our Phase 1 trial of GR-MD-02 in NASH patients with advanced fibrosis was a success in all key measures of safety and pharmacokinetics, while the exploratory marker A2M and non-invasive liver stiffness measure via FibroScan® are encouraging," said Peter G. Traber, M.D., Chief Executive Officer, President and Chief Medical Officer of Galectin Therapeutics. "The additional finding in the third cohort that liver stiffness may be decreased following administration of GR-MD-02 is an exciting one that opens additional avenues for Phase 2 study designs. The results of the Phase 1 trial provide the basis for launching a Phase 2 program that will include several concurrent trials focused on NASH patients with advanced fibrosis and cirrhosis. We plan to announce details of the Phase 2 program in February 2015 and to initiate trials in the second quarter of 2015."

Dr. Traber added, "I extend sincere thanks to three groups for their involvement in this study. First and most importantly, I thank the patients who donated time and effort to help promote a promising therapy - their dedication to our protocol is recognized as critical to progress. Second, I thank the world-class group of investigators and their support teams who worked on this trial. Lastly, I thank Clinical Trial and Consulting Services, who as our contract research partner worked tirelessly to accomplish these results."

The Phase 1 multicenter, double-blind, placebo-controlled clinical trial was conducted in patients with NASH with advanced fibrosis (Brunt Stage 3) who received four doses of GR-MD-02 over a 35- to 42-day period. Each of the three planned cohorts consisted of patients randomized to receive active drug or placebo. Trial design details can be found here.

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

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 9 to 15 million people in the U.S., including children. 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 3 million individuals will develop cirrhosis, a severe liver disease where 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, key mediators of biologic function. Galectin is leveraging 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 clear 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 fibrosis. 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 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, 2013, 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.

CONTACT: Galectin Therapeutics Inc.

Peter G. Traber, M.D.

President, CEO & CMO

(678) 620-3186

ir@galectintherapeutics.com

LHA

Kim Golodetz

(212) 838-3777

kgolodetz@lhai.com

Source: Galectin Therapeutics, Inc.