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Galectin Therapeutics' Phase 1 Data Presented at AASLD Annual Meeting Advances GR-MD-02 Into Phase 2 Clinical Development

NORCROSS, Ga., Nov. 9, 2014 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, presented data today from the Company's Phase 1 clinical trial of GR-MD-02 in NASH (fatty liver disease) patients with advanced fibrosis at The Liver Meeting in Boston, Massachusetts. Stephen A. Harrison, MD, Chief of Hepatology at Brooke Army Medical Center in Fort Sam Houston and a clinical trial investigator in Galectin Therapeutics' Phase 1 clinical trial, shared the data during an oral presentation at the 65th Annual Meeting of the American Association for the Study of Liver Diseases.

The Phase 1 first-in-man study evaluated the safety, tolerability, and drug pharmacokinetics for single and multiple doses of galectin-inhibiting drug GR-MD-02 when administered to patients with NASH (fatty liver disease) with advanced fibrosis. Additionally, exploratory serum biomarkers were evaluated as potential tools that may be used to aid in future studies. Dr. Harrison reviewed previously-reported results from the ongoing Phase 1 clinical trial including completed cohorts 1 and 2 and also presented, for the first time, interim data from completed patients from cohort 3. In the three-cohort design, eight patients (6 active drug and 2 placebo) completed cohort 1 at the 2 mg/kg dosage; nine patients (7 active drug and 2 placebo) completed cohort 2 at the 4 mg/kg dosage; and nine patients (6 active drug and 3 placebo) have so far completed cohort 3 at the 8 mg/kg dosage. Therefore, there was a similar number of patients from each of the cohorts for comparison purposes.

Overall, data from the multi-center, partially blinded Phase 1 trial showed that administration of 2, 4 and 8 mg/kg lean body weight of GR-MD-02 intravenously for four doses over 6 weeks was safe and well tolerated. Thus, the primary endpoint of the study has been met. There were no serious adverse events reported in any of the three cohorts and mild (grade 1) adverse events possibly related to study drug were found in 3 placebo patients and only 2 patients receiving active drug.

In cohorts 1 and 2, pharmacokinetic data demonstrated a proportional increase in total drug exposure with doubling of the dose of GR-MD-02 with no accumulation after four doses. In newly released data from cohort 3, Dr. Harrison reported that pharmacokinetic analysis of GR-MD-02 plasma levels for the 8 mg/kg dose provides drug coverage in the upper portion of the targeted therapeutic range derived from NASH animal model studies.

An evaluation of exploratory serum biomarkers in all three cohorts revealed that the vast majority of biomarkers do not seem to be useful tools to aid in the design of short-term therapeutic trials. These exploratory biomarkers showed marked variability over time in placebo patients as well as active drug patients.

In contrast to other biomarkers, FibroTest®, a composite score that has been correlated with the extent of liver fibrosis, was significantly reduced by GR-MD-02 treatment in cohort 3. The treatment effect on FibroTest score was due to a statistically significant reduction of alpha-2 macroglobulin, one of the components of the score. This reduction in FibroTest score and alpha-2 macroglobulin was only seen in the high dose cohort 3 and not in cohort 1 and 2.

According to Dr. Harrison, "Today's presentation to the scientific community at AASLD reveals key insight into the safe use of GR-MD-02 on fatty liver disease in advanced fibrosis. The objective of the Phase 1 trial is to evaluate safety and pharmacokinetics of GR-MD-02. What we have seen so far in the Phase 1 trial is that GR-MD-02 is safe and well tolerated at multiple doses. It was an added bonus that we found a reduction for serum biomarker alpha-2 macroglobulin."

"The company is planning to initiate a Phase 2 clinical trial in the second quarter of 2015 based on the robust pre-clinical effects of the drug and these successful Phase 1 results," said Peter G. Traber, M.D., Chief Executive Officer, President and Chief Medical Officer of Galectin Therapeutics. "Following a recent meeting with the U.S. Food and Drug Administration, the company has determined its Phase 2 trial will be in NASH patients with cirrhosis with evaluation of portal hypertension (hepatic venous pressure gradient) as the primary surrogate endpoint and the amount of collagen, as determined by digital morphometric analysis, as a key secondary endpoint. Additional non-invasive measures of liver function and structure will also be assessed. Further details of the Phase 2 clinical trial will be announced prior to initiation. Given the positive results reviewed at AASLD today, cohort 3 of the Phase 1 trial will be ended after the completion of an additional four patients that have been enrolled (13 patients total in cohort 3)."

Dr. Traber added, "I want to sincerely thank three groups for their involvement in this study. First, and most importantly, I thank the individual patients who donated their time and effort to help advance a promising therapy—their contribution was critical to the Company's progress in development of GR-MD-02. Second, I thank the world-class group of investigators and their support groups who worked on this trial. Finally, CTI as our CRO partner worked tirelessly to accomplish the results."

GR-MD-02 is Galectin Therapeutics' patented, proprietary molecule derived from apple pectin material that binds to and inhibits galectin proteins, predominantly galectin-3.

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, estimated to affect nine to 15 million people, including children, 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 drink 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 three million individuals will develop cirrhosis, a severe liver disease where liver transplantation is the only current treatment available. Approximately 6,300 liver transplants are done on an annual basis in the U.S. There are no drug therapies approved for the treatment of liver fibrosis.

About Galectin Therapeutics

Galectin Therapeutics (Nasdaq:GALT) 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. We are leveraging extensive scientific and development expertise as well as established relationships with external sources to achieve cost effective and efficient development. We are pursuing a clear development pathway to clinical enhancement and commercialization for our lead compounds in liver fibrosis and cancer. Additional information is available at www.galectintherapeutics.com.

Forward Looking Statements

This press release contains, in addition to historical information, 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 our current expectations and are subject to factors and uncertainties which could cause actual results to differ materially from those described in the statements. These statements include those regarding our plans, expectations and goals regarding clinical trials, including our expectation that a final clinical data report from the third cohort should be available in January 2015, plans regarding design and composition and timing of a Phase 2 clinical trial, and plans regarding future funding alternatives and the sufficiency of cash on hand to fund future operations and planned research and development through mid-2016. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that our plans, expectations and goals regarding any clinical trial or any future trials are subject to factors beyond our control and there is no guarantee that we will avoid delays in the development of our drug products or receive FDA approval for any of our drugs in development. Any current clinical trials and any future trials may not produce positive results in a timely fashion, if at all, and any necessary changes during the course of a trial could prove time consuming and costly. We may have difficulty in enrolling candidates for testing, which would impact our estimates regarding timing, and we may not be able to achieve the desired results. Upon receipt of FDA approval, we may face competition with other drugs and treatments that are currently approved or those that are currently in development, which could have an adverse impact on our ability to achieve revenues from any proposed indications. Plans regarding development, approval and marketing of any of our drugs, including GR-MD-02, are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies. To date, we have incurred operating losses since our inception, and our ability to successfully develop and market drugs may be impacted by our ability to manage costs and finance our continuing operations. For a discussion of additional factors impacting our business, see our Annual Report on Form 10-K for the year ended December 31, 2013, and our subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause our views to change, we disclaim any obligation to update forward-looking statements.

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