July 30, 2014

Galectin Therapeutics Issues Statement on GR-MD-02 Development Program

NORCROSS, Ga., July 30, 2014 (GLOBE NEWSWIRE) -- Galectin Therapeutics (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announced yesterday results of cohort 2 of its phase 1 clinical trial in patients with NASH with advanced fibrosis. While the results of the clinical trial were positive, the market reacted negatively to this report. We believe the reaction was fueled in part by certain commentary on social media sites and the Internet and we strongly disagree with these interpretations of our data. Our goal in commenting further at this juncture is to provide clarity and a helpful framework for investors on the long-term outlook of the company and our work toward developing potential therapies for NASH and liver fibrosis.

GR-MD-02 is a complex carbohydrate molecule derived from apple pectin material that binds to galectin-3 protein thereby inhibiting its activity. There is a large amount of scientific literature showing galectin-3 is a critical protein in fibrosis. While certain commentators on social media sites have dubbed it a "non-mechanism of action," this view contradicts many peer reviewed published studies. The phase 1 clinical trial was the first time this molecule was infused into man. Comments on social media about the drug being a "sugar placebo" are misguided and anti-intellectual. GR-MD-02 has been shown to be effective in treating NASH and fibrosis when infused in several animal models, results of which have been reported in peer review scientific journals and presented at international scientific meetings. Based on the pre-clinical data and the enormous need for drugs in an area where there is no therapy, the FDA gave development of GR-MD-02 for NASH with advanced fibrosis Fast Track designation. The importance of galectin-3 in fibrosis and the mechanism of action and the drug action are on a firm scientific foundation.

Certain commentators on social media labeled the second cohort results, "a flop." This is simply not accurate. The primary endpoints for the phase 1 trial have always been safety and pharmacokinetics and have been successfully met for each cohort completed. The dose of 4 mg/kg was safe and well tolerated and drug levels showed that the drug acted predictably and with a linear increase from the 2 mg/kg dose. While the phase 1 trial is still ongoing, we deem the phase 1 clinical trial a success up to this point.

This phase 1 clinical trial, and in fact all phase 1 clinical trials, are not designed to demonstrate efficacy of a drug. Phase 2 clinical trials are designed to evaluate efficacy of a drug, and our phase 2 clinical trial(s) will follow the completion of this phase 1 trial. Having said this, often a number of exploratory biomarkers are included to determine whether there is some evidence of effect. Exploratory means that there is some scientific evidence that they may provide useful information, but they have not been studied sufficiently to be used as definitive evidence of disease treatment. In fact, in the case of NASH with advanced fibrosis there are no biomarkers that have been shown to change with a short-term treatment. Exploratory biomarker data in our trial do show evidence of some drug effect, but direct comparison of the first and second cohorts was not possible because the timing of the blood draws. Was this a mistake to change the timing of the biomarkers? No, it was not because we are "exploring" how to best use these biomarkers. Because of the differences between the two cohorts, the third cohort will now have 4 evaluations of biomarkers instead of 2 on a larger group of patients. Why didn't we do more evaluations of biomarkers in the second cohort? Had we done this, and obtained the requisite approval from eight different institutional review boards, the second cohort would have been delayed for up to 2 months. The better approach, in our judgment, was not to spend the time to make these changes and just to make the added blood draws in the third cohort. The critical point is that exploratory biomarkers were included to aid in the design of a phase 2 program that will be focused on showing efficacy, and for this they are serving their purpose.

The question has been asked, "Without clear biomarker changes, how will you choose doses for a phase 2 trial?" We are not dependent on biomarker data for a phase 2 clinical trial. We have a very clear understanding of drug doses and serum drug levels that are associated with a therapeutic effect in animal studies. From the phase 1 clinical trial, we now know that the doses used in man straddle the therapeutic doses used in animals, thus providing the information for choosing doses for a phase 2 clinical trial. The pharmacokinetic data from cohort 3 of the Phase 1 trial are expected to add further to our knowledge about dose selection for the Phase 2 trial (s).

Certain commentators on social media dubbed the drug a "failure" because galectin-3 levels in the blood did not change. This is an incorrect interpretation of our data. As we explained in our webcast when we announced the results of cohort 1 and 2, we do not expect galectin-3 levels in the blood to change with the extent of liver disease. We have shown in animals that there are high levels of galectin-3 in diseased livers, but there is no change in blood levels. Further, we have shown directly that the tissue levels of galectin-3 in the liver are reduced on treatment with GR-MD-02, whereas serum levels are not. Moreover, there are studies from other investigators showing that blood galectin-3 levels do not correlate with liver disease severity in NASH. No change in galectin-3 blood levels is the expected result.

The development program for GR-MD-02 for NASH with advanced fibrosis remains on track. Far from a "flop", the phase 1 clinical trial, including both cohorts, has been a success. We now have a range of safe doses that can be used in a phase 2 clinical trial and the third cohort will further add to our pharmacokinetic knowledge and guide appropriate dose selection for Phase 2. Upon completion of the third cohort, which has already infused two patients, we will initiate a phase 2 clinical trial program to definitively evaluate the therapeutic potential of this promising therapy using a standard endpoint of liver biopsy to assess efficacy. Planning for the phase 2 trial is underway utilizing the knowledge gained from the Phase 1 trial, to date.

"We are extremely pleased with the progress of our development program in NASH with advanced liver fibrosis," said Peter G. Traber, M.D., Chief Executive Officer, President and Chief Medical Officer of Galectin Therapeutics. "This represents a significant area of unmet medical need, and while there are a number of companies exploring various approaches for therapy, there are no therapies that are near to market, no therapies that have been tested using relevant clinical endpoints, nor any treatments even in phase 3 of development. I am proud of the small, dedicated group of medical and scientific individuals who have worked painstakingly on this program with the hope of bringing an important therapy to patients with NASH with advanced fibrosis. Moreover, we sincerely appreciate the advice, dedication, and support of our investigators and their site personnel and importantly that of their NASH patients who willingly gave their time and energy to help advance our therapy and help others with this this disease."

On another front, Galectin has been criticized in the media for the use of "an ugly, penny stock promotion scheme." This is a complete misrepresentation. Small companies often use various approaches to publicize what they are doing and why it may be important for medicine. Because it is costly to have full investor relations functions staffed within the company, companies often use external publicity firms. Emerging Growth LLC was engaged by Galectin to write factual stories related to the company's programs and attract individuals who would be interested in following the Company's progress. Emerging Growth has written approximately 13 articles on the company since it began representing Galectin in public relation activities since June 2013, and the company never discloses nonpublic material information to Emerging Growth. The articles were written by Emerging Growth LLC using only information in the public domain and comparing and contrasting Galectin's program with others in the field. Disclaimers were provided by Emerging Growth LLC that Galectin paid $3500 monthly for this service. The characterization that this practice is a "scheme," implying an illegal activity, is just not correct. Again, we believe our decision to contract for certain public relations activities, rather than attempting to staff them in-house, is a legal, appropriate and prudent use of our resources.

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 drug development program and our clinical trial. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that we may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of GR-MD-02 or any of our other drugs in development. Our 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 our drugs are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies. Regardless of the results of any of our development programs, we may be unsuccessful in developing partnerships with other companies that would allow us to further develop and/or fund any studies or trials. 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.

CONTACT: Galectin Therapeutics Inc.

Peter G. Traber, MD, 678-620-3186

President, CEO, & CMO

ir@galectintherapeutics.com