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Galectin Therapeutics Announces That Oral Treatment With Galectin-3 Inhibitor GR-MD-02 is Efficacious in Preclinical Model of Fatty Liver Disease With Fibrosis

NORCROSS, Ga., June 23, 2014 (GLOBE NEWSWIRE) -- Galectin Therapeutics (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announced today that a preclinical study in a mouse model of NASH (non-alcoholic steatohepatitis, or fatty liver disease) demonstrated that oral administration of the Company's lead galectin-3 inhibitor, GR-MD-02, resulted in significant disease improvement.

Diabetic mice, fed a high fat diet to induce NASH, were treated after the development of disease with either a vehicle control (n=8) or GR-MD-02 (n=9) administered orally five days out of seven for a total of four weeks. The liver weight, liver-to-body weight ratio, and plasma triglyceride levels were significantly reduced in the GR-MD-02 treated animals as compared to vehicle control animals ($p < 0.05$). Blood indicators of liver damage, including plasma AST (aspartate aminotransferase), plasma ALT (alanine aminotransferase), and plasma total bilirubin (TB) also demonstrated a statistically significant reduction following oral treatment with GR-MD-02 and, in fact, levels were reduced back to near normal levels (see accompanying figure here). AST, ALT, and TB in normal animals (140 ± 86 U/L, 33 ± 8 U/L, 0.4 ± 0.0 mg/dL) were increased in the NASH animals treated with vehicle (293 ± 59 U/L, 87 ± 16 U/L, 0.56 ± 0.1 mg/dL) and were significantly reduced with oral GR-MD-02 treatment (159 ± 27 U/L, $p < 0.01$; 46 ± 12 U/L, $p < 0.01$; 0.4 ± 0.1 mg/dL, $p < 0.001$). Each of these blood biomarkers indicate liver injury that improved with treatment.

Finally, fibrosis of the liver was significantly reduced with treatment with GR-MD-02, as indicated by the liver hydroxyproline content, a biochemical marker of collagen in the liver. Liver hydroxyproline content in the normal liver (0.48 ± 0.07 µg/mg total protein) was increased in the NASH animals treated with vehicle (0.76 ± 0.14 µg/mg total protein) and was significantly reduced with oral GR-MD-02 treatment (0.56 ± 0.12 µg/mg total protein, $p < 0.01$).

"Oral activity of GR-MD-02 in this established preclinical model of NASH represents an important step in the development of galectin inhibitors and complements our ongoing clinical program of intravenous administration in patients with NASH with advanced fibrosis," said Dr. Peter G. Traber, President, Chief Executive Officer, and Chief Medical Officer of Galectin Therapeutics Inc. "We have evaluated various established technology platforms and are currently developing oral formulations with a contracted firm with the goal of developing an oral formulation for human studies as a follow on to our current clinical development program."

The Company has an ongoing clinical trial of GR-MD-02 titled, "A Multi-Center, Partially Blinded, Maximum Tolerated Multiple Dose Escalation, Phase 1 Clinical Trial to Evaluate the Safety of GR-MD-02 in Subjects with Non-Alcoholic Steatohepatitis (NASH) with Advanced Hepatic Fibrosis." Trial design details can be found at http://clinicaltrials.gov/ct2/show/NCT01899859?term=gt-020&rank=1. In 2013, Galectin Therapeutics received Fast Track designation from the FDA for this clinical development program. FDA grants Fast Track designation to help expedite review and approval of drugs in development that treat serious or life threatening diseases and fill an unmet medical need.

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," "anticipated," "expect" and others. They are based on our 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 pre-clinical and clinical trials, expectations regarding our drug development program, possible benefits of our drugs and therapies, and estimates regarding those impacted by disease. 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 pre-clinical and clinical trials and any future pre-clinical or 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.

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