



August 12, 2013

## **Galectin Therapeutics Receives FDA Fast Track Designation for GR-MD-02 for Fatty Liver Disease With Advanced Fibrosis**

NORCROSS, Ga., Aug. 12, 2013 (GLOBE NEWSWIRE) -- Galectin Therapeutics (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted GR-MD-02 (galactoarabino-rhamnogalacturonate) Fast Track designation for non-alcoholic steatohepatitis (NASH) with hepatic fibrosis, commonly known as fatty liver disease with advanced fibrosis.

Galectin Therapeutics is currently conducting a Phase 1 clinical trial to evaluate the safety, tolerability and exploratory biomarkers for efficacy for single and multiple doses of GR-MD-02 over four weekly doses of GR-MD-02 treatment in patients with fatty liver disease with advanced fibrosis. The study will enroll eight patients in each dose escalation cohort and there will be at least three cohorts and potentially up to five cohorts, with a maximum of 40 patients at six clinical sites in the US, which each have extensive experience in clinical trials in liver disease. More information on the first-in-man Phase 1 clinical study of GR-MD-02 is available at <http://clinicaltrials.gov/ct2/show/NCT01899859?term=gt-020&rank=1>.

"Our preclinical data has shown that GR-MD-02 has robust treatment effects in reversing fibrosis and cirrhosis. Fast Track designation enables us to expedite the compound's development and review process, with the ultimate goal of bringing a first-in-class treatment to the millions of Americans suffering from fatty liver disease with advanced fibrosis," said Dr. Peter G. Traber, President, Chief Executive Officer, and Chief Medical Officer of Galectin Therapeutics Inc. "We are very pleased that the FDA sees the clinical value of GR-MD-02 and seriousness of fatty liver disease, and we look forward to working closely with the FDA throughout this process."

The FDA's Fast Track program is designed to expedite the review of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs.

### **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 proteins play a major role in diseases that involve scarring of organs such as cancer, and inflammatory and fibrotic disorders. The drug binds to galectin proteins and disrupts their function. Preclinical data has shown that GR-MD-02 has robust treatment effects in reversing fibrosis and cirrhosis in kidney, lung, and liver.

### **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 US. 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 US. 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](http://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 plans, expectations and goals, expectations and goals regarding the clinical trial, our FAST TRACK submission and the potential benefits of a FAST TRACK designation, potential therapeutic uses and benefits of our

galectin inhibitors and further related studies and potential partnerships. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that the receipt of a FAST TRACK designation from FDA is no guarantee that we avoid delays in the development of our drug product and provide no assurance of FDA approval of our drug development plans and of the grant of marketing approval for our drug product. Future clinical studies may not begin or 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 current or future studies, 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, 2012, 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](mailto:ir@galectintherapeutics.com)