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Galectin Therapeutics Receives US Patent for Potential Ground-Breaking Treatment for Fatty Liver Disease

NORCROSS, Ga., Sept. 10, 2013 (GLOBE NEWSWIRE) -- Galectin Therapeutics (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today announced that it has received a notice of issuance from the U.S. Patent and Trademark Office for Patent Application Number 13/573,454 titled "Galacto-rhamnogalacturonate compositions for the treatment of non-alcoholic steatohepatitis and non-alcoholic fatty liver disease." The patent covers the Company's carbohydrate-based galectin inhibitor compound GR-MD-02 for use in patients with fatty liver disease with or without fibrosis or cirrhosis. Fatty liver disease affects as many as 15 million Americans, results in severe scarring of the liver (cirrhosis), and there are no currently approved pharmaceutical therapies.

The U.S. Food and Drug Administration (FDA) recently granted GR-MD-02 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 issuance of this patent provides broad coverage in the U.S. for the use of GR-MD-02 in fatty liver disease through September 2031 and international patent coverage is pending for the same intellectual property," said Peter G. Traber, MD, President, CEO and CMO of Galectin Therapeutics. "There is a truly vast unmet medical need for the treatment of fatty liver disease with fibrosis, as the most prevalent liver disease in the U.S. We are hopeful that our development program for GR-MD-02 will lead to the first therapy for this unmet medical need."

The patent inventors include Peter Traber, Eliezer Zomer and Anatole Klyosov with assignment to Galectin Therapeutics. The major claims are for methods of obtaining galectin inhibitor compounds, obtaining a composition for parenteral or enteral administration in an acceptable pharmaceutical carrier and administering to a subject having at least one of the following: fatty liver, non-alcoholic fatty liver disease, non-alcoholic steatohepatitis, non-alcoholic hepatitis with liver fibrosis, non-alcoholic steatohepatitis with cirrhosis, or non-alcoholic steatohepatitis with cirrhosis and hepatocellular carcinoma. The use covers reversing or slowing the progression of disease activity or medical consequences of the disease. Moreover, additional claims cover the use of the galectin inhibitor compounds in combination with multiple other agents that may have potential activity in the disease that are under investigation elsewhere.

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. FDA and AASLD (American Association for the Study of Liver Disease) recently held a 2-day workshop with leading scientific experts in NASH and key FDA officials to discuss acceptable regulatory endpoints for approval of drugs to treat NASH (<http://www.aasld.org/additionalmeetings/Pages/aasldfdanash.aspx>).

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 the hope that our 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 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, 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.

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