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## Galectin Therapeutics Begins Phase 2a Psoriasis Study With GR-MD-02

# Proof-of-Concept Study to Determine Safety and Efficacy in 10 Patients With Moderate-to-Severe Plaque Psoriasis

NORCROSS, Ga., Sept. 24, 2015 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announces the start of a 10-patient pilot study with GR-MD-02 in patients with moderate-to-severe plaque psoriasis.

The genesis of this study is the apparent remission of a patient with severe psoriasis who participated in the Company's Phase 1 study cohort of 4 mg/kg of GR-MD-02 for the treatment of non-alcoholic steatohepatitis (NASH). That patient received her fourth infusion of GR-MD-02 in May 2014, and her psoriasis remained in complete remission for 17 months, with slight scaling becoming evident on her elbows just this month.

"We are excited to begin this study at the Brooke Army Medical Center in San Antonio, Texas," said Peter G. Traber, M.D., Galectin's president, chief executive officer and chief medical officer. "We know from the scientific literature that galectin-3 is at higher levels in the skin of psoriasis patients, and that GR-MD-02 inhibits galectin-3. It would follow that GR-MD-02 could affect this disease. We are hopeful that patients with moderate-to-severe plaque psoriasis will show a clearing of their disease without the negative side effects associated with many of the currently available therapies. In addition, a successful pilot study would add to our robust therapeutic pipeline for this compound."

Psoriasis, which manifests most often as plaque psoriasis, is a chronic, relapsing, inflammatory skin disorder. Although plaque psoriasis is rarely life threatening, it often is intractable to treatment. According to the International Federation of Psoriasis Associations, about 3% of the world's population has some form of psoriasis. In the U.S. there are about 150,000 new cases every year, and psoriasis affects about 2% of the population, according to the Cleveland Clinic.

#### **About the Psoriasis Study**

This study is a Phase 2a open-label trial in patients with moderate-to-severe plaque psoriasis in which 10 psoriasis patients with  $\geq$  10% of their skin affected and a PASI (psoriasis activity and severity index) of  $\geq$  12 points will be treated with 8 mg/kg of GR-MD-02 every other week for a total of seven infusions. The primary endpoint will be the PASI-75, or a 75% improvement in the severity of the disease 30 days following the final infusion. More information on the trial can be found in a CEO Perspective published today, which can be found <a href="here">here</a>.

#### 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-3 plays a major role in diseases that involve scaring of organs including fibrotic disorders of the liver, lung, kidney, heart and vascular system. The drug binds to galectin proteins and disrupts their function. Preclinical data in animals have shown that GR-MD-02 has robust treatment effects in reversing liver fibrosis and cirrhosis.

#### **About Galectin Therapeutics**

Galectin Therapeutics 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, which are key mediators of biologic function. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. The Company is pursuing a development pathway to clinical enhancement and commercialization for its lead compounds in liver fibrosis and cancer. Additional information is available at <a href="https://www.galectintherapeutics.com">www.galectintherapeutics.com</a>.

### **Forward Looking Statements**

This press release contains 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 management's 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 the hope that Galectin's development program for GR-MD-02 will lead to an additional therapy for the

treatment of psoriasis as well as the first therapy for the treatment of fatty liver disease with cirrhosis. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of GR-MD-02 or any of its other drugs in development for the treatment of psoriasis, fatty liver disease with cirrhosis or other diseases. The Company's current clinical trials 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 Galectin's drugs are subject to change at any time based on the changing needs of the Company as determined by management and regulatory agencies. There are a number of drugs available for the treatment of psoriasis, which may affect both the approval of GR-MD-02 for the treatment of psoriasis and the subsequent marketing of it. Regardless of the results of any of its development programs. Galectin may be unsuccessful in developing partnerships with other companies or raising additional capital that would allow it to further develop and/or fund any studies or trials. Galectin has incurred operating losses since inception, and its ability to successfully develop and market drugs may be impacted by its ability to manage costs and finance continuing operations. For a discussion of additional factors impacting Galectin's business, see the Company's Annual Report on Form 10-K for the year ended December 31, 2014, and subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

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