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Galectin Therapeutics Reports no Drug-Drug Interaction Between GR-MD-02 and Midazolam

Phase 1 Pharmacokinetic Study Conducted in Accordance With FDA Requirements; Results Add to the GR-MD-02 Safety Profile and Allow for Expansion of Number of Patients Eligible to be Included in Phase 2 Clinical Trials

NORCROSS, Ga., May 14, 2015 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, reports that in an open-label Phase 1 study with 8 mg/kg dose of GR-MD-02 and 2 mg/kg dose of midazolam there was no drug-drug interaction and no serious adverse events or drug-related adverse events were observed. This study was required by the U.S. Food and Drug Administration (FDA) and the primary objective was to determine if single or multiple intravenous (IV) doses of GR-MD-02 affect the pharmacokinetics (PK) of midazolam. The secondary objective was to assess the safety and tolerability of GR-MD-02 when administered concomitantly with midazolam.

The lack of a drug interaction in this study will permit Galectin to expand the number of patients eligible for its Phase 2 clinical trial. In addition, should GR-MD-02 be approved for marketing, the success of this study supports a broader patient population for the drug label.

"The success of this study is important to the advancement of GR-MD-02 as a treatment for non-alcoholic steatohepatitis (NASH) with fibrosis and/or cirrhosis because midazolam is widely used in clinical practice for mild, conscious sedation. Importantly, midazolam provides a good model for many other commonly used drugs that are metabolized by the CYP3A4 enzyme system, to which patients with liver disease might be exposed to for a variety of clinical indications," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. "We are very pleased to find no pharmacokinetic issues with GR-MD-02 and midazolam following single and multiple doses of both drugs. The rigorous conduct of this study was a requirement by the FDA and overcomes one more important hurdle in our efforts to bring a drug to address the needs of a growing number of patients who develop NASH, and subsequently progress to liver fibrosis and cirrhosis."

The open-label Phase 1 study in normal healthy volunteer subjects tested a single dose of IV midazolam in the absence of GR-MD-02, following a single IV dose of GR-MD-02 and following three weekly IV doses of GR-MD-02. The four dosing periods were spaced one week apart, with midazolam PK determined in dosing periods one, two and four. A total of 17 subjects completed the study and met the primary endpoint of midazolam clearance when administered alone, compared with when administered with single and multiple doses of GR-MD-02. Drug to drug interaction studies are an integral part of understanding how a drug will affect patients who are also on other drugs. With completion of this study, the company does not anticipate further drug-drug interaction studies will be required in the development of GR-MD-02.

Dr. Traber added, "We are preparing to begin patient screening for our Phase 2 program in the coming weeks, which consists of a study in patients with NASH cirrhosis and a study in NASH patients with advanced fibrosis, but not cirrhosis. It should be noted as we embark on the next steps of our development strategy that Galectin has significantly invested in the chemical and pharmaceutical development of our compound, has implemented analytical methods to meet FDA requirements and is continually generating the necessary data to adequately characterize our drug compound. When a new chemical entity is chosen and defined as a potential drug candidate, the drug must be fully characterized. This drug characterization is necessary to understand the behavior of the drug, in solid state (drug substance) as well as in solution (drug product). Our working relationships with academic institutions and commercial analytical organizations with expertise in carbohydrate chemistry and analytical characterization of complex carbohydrate molecules helps to assure that our products are adequately characterized using the latest available technologies."

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 www.galectintherapeutics.com.

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 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. The Company's 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 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. Carbohydrates are a relatively new drug class, and regulatory requirements are evolving; we cannot assure that we will be able to meet such requirements in a timely and cost effective manner in the manufacturing and characterization of our products. 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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