January 31, 2013

Galectin Therapeutics Inc. Announces Submission of an Investigational New Drug (IND) Application for the Treatment of Fatty Liver Disease

NORCROSS, Ga.--(BUSINESS WIRE)--Jan. 31, 2013-- Galectin Therapeutics (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announced today that it submitted an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) on January 30, 2013. The IND application supports a proposed indication of GR-MD-02 for treatment of non-alcoholic steatohepatitis (NASH) with advanced fibrosis, or fatty liver disease.

“This IND submission is the first step in the clinical development program of GR-MD-02 for the treatment of liver fibrosis,” said Dr. Peter G. Traber, President, Chief Executive Officer, and Chief Medical Officer of Galectin Therapeutics Inc. “We are leveraging our leadership in galectin science to bring new treatment options for these severely underserved patients and strongly believe that our novel approach of inhibiting galectin may be the key to the prevention and reversal of liver fibrosis.”

The IND application includes twenty seven (27) individual studies that characterize the pharmacology, pharmacokinetics, and toxicology of GR-MD-02 in a number of animal species, including the effects in various animal models of disease. Additionally, the application describes the manufacture of the drug substance and drug product to be used in human clinical trials. This information provides a description of how the drug works and why we believe it is likely to be safe in humans and provides a description of its possible mechanism of action in humans. The main purpose of the IND is to share with the FDA the extensive non-clinical data that we believe predicts for an acceptable safety profile when GR-MD-02 is first administered to humans in the initial early-stage clinical studies. The FDA will review this application and determine the acceptability of the data to predict the safety of GR-MD-02 before Galectin Therapeutics begins an initial human Phase 1 clinical trial. It is possible that the FDA will require additional information. If the FDA determines that the submitted package of data is acceptable, the Company plans on proceeding with a Phase 1 clinical trial. Future communications will outline study design and timing.

About NASH

NASH has become a common disease of the liver with the rise in obesity rates, affecting 9 to 15 million people, including children, in the United States. NASH 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 NASH can develop fibrosis, or scarring of the liver, and it is estimated that as many as 3,000,000 will develop cirrhosis, a severe liver disease where transplantation is the only current treatment available. Approximately 6,300 liver transplants are done on an annual basis in the United States.

About Galectin Therapeutics Inc.

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, statements that look forward in time or that express management’s beliefs, expectations or hopes. Such statements are 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 risks and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include our goals regarding the IND application, our plans for a clinical trial and estimates regarding those impacted by NASH. Our goals regarding the proposed indication of GR-MD-02 and related trials and approval are subject to factors beyond our control. Our IND application may not be approved in a timely fashion, if at all, and the FDA may require changes to our application that could prove time consuming and costly. To the degree we are able to conduct clinical trials, we may have difficulty in enrolling candidates for testing and we may not be able to achieve the desired results. Upon receipt of FDA approval, we may face competition with other drugs and treatments that are currently approved or those that are currently in development, which could have an adverse impact on our ability to achieve revenues from this proposed indication. Plans regarding development, approval and marketing of any of our drugs, including GR-MD-02, are subject to change at any time based on the changing needs of our company as determined by management. 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, 2011, 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.

Source: Galectin Therapeutics Inc.

Galectin Therapeutics Inc.

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