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Galectin Therapeutics Submits Fast Track Application to FDA for GR-MD-02 in Treatment of Fatty Liver Disease with Advanced Fibrosis

NORCROSS, Ga., July 1, 2013 /PRNewswire/ -- Galectin Therapeutics (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announced today that it has submitted a Fast Track application to the FDA to help expedite its clinical development program of GR-MD-02 in the treatment of non-alcoholic steatohepatitis (NASH, or fatty liver disease) with advanced fibrosis. FDA grants Fast Track designation to help expedite review and approval of drugs in development that treat serious or life threatening diseases and fill an unmet medical need. GR-MD-02 has shown robust treatment effects in reversing fibrosis and cirrhosis in pre-clinical studies and a phase 1 clinical trial in patients with NASH with advanced fibrosis is currently enrolling.

"There are currently no approved medical treatments available for the millions of patients in the US who have NASH with advanced fibrosis," said Dr. Peter G. Traber, President, Chief Executive Officer, and Chief Medical Officer of Galectin Therapeutics Inc. "Fast Track designation from FDA would effectively open many important regulatory pathways to efficiently expedite patient access and will be highly beneficial to advancing the development program for GR-MD-02 in the treatment of NASH with advanced fibrosis."

A drug that receives Fast Track designation is eligible for many regulatory benefits from the FDA that can lead to earlier drug approval and access by patients, including more frequent meetings and interactions with the Agency during development to ensure appropriate clinical design and data collection. Drugs receiving Fast Track status are also eligible for Rolling Review, Priority Review, and Accelerated Approval pathways. FDA's Rolling Review process allows a drug company to submit completed sections of its New Drug Application (NDA) for review rather than waiting until every section of the application is completed. Priority Review allows the FDA to reduce the time to review a new drug application, with a completion goal of six months from the 60 day filing date, as opposed to 10 months from the 60 day filing date for the current standard review. An Accelerated Approval pathway is an option for approval based on demonstrating an effect on a surrogate, or substitute endpoint reasonably likely to predict clinical benefit. For further information, please see http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccesstoImportantNewTherapies/ucm128291.htm.

In accordance with "FDA Guidance for Industry: Fast Track Drug Development Programs —Designation, Development, and Application Review," the Agency will respond to a request for Fast Track designation within 60 calendar days of receipt of the request. A designation letter from FDA will help facilitate the development of GR-MD-02; the purpose of the Fast Track process being to get important new drugs to the patient earlier.

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. Follow us on Twitter @GalectinGALT.

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 those regarding our FAST TRACK submission and the potential benefits of a FAST TRACK designation, as well as our estimates regarding those impacted by NASH. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that receipt of a FAST TRACK designation from the FDA is beyond our control and the FDA may not approve our application. Also, regardless of whether we receive FAST TRACK designation, our clinical trial may not produce positive results in a timely fashion, if at all, and any necessary changes during the course of the trial

could prove time consuming and costly. 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 and regulatory agencies. 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.

SOURCE Galectin Therapeutics