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Galectin Therapeutics Planning Clinical Trials for Early 2013 to Treat Fatty Liver Disease with Advanced Fibrosis After Recent FDA Meeting

NEWTON, Mass.--(BUSINESS WIRE)--Aug. 7, 2012-- Galectin Therapeutics (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today announced its clinical development program for the treatment of non-alcoholic steatohepatitis (NASH), or fatty liver disease, with advanced fibrosis. Galectin Therapeutics has selected GR-MD-02, a novel galectin inhibitor discovered by the Company, as its lead candidate for NASH, which is expected to enter clinical trials in early 2013. NASH represents a major unmet medical need, affecting 9 to 15 million Americans, with the only treatment option being liver transplantation.

“Patients who undergo liver transplantation for advanced fibrosis carry a high possibility of disease recurrence because the underlying cause of the fibrosis is not addressed,” said Peter G. Traber, MD, President, CEO and CMO of Galectin Therapeutics. “GR-MD-02 has demonstrated the ability to not only prevent, but reverse liver fibrosis in preclinical mouse models of NASH, suggesting that this candidate could represent a disease-modifying treatment option. We are currently conducting the final preclinical studies and have trial design guidance from the Food and Drug Administration which will support an IND submission by the end of 2012.”

GR-MD-02 is a carbohydrate-based candidate that inhibits galectins, key modulators of liver fibrosis. In several preclinical studies, GR-MD-02 was able to prevent and reverse liver fibrosis in mouse models of NASH. In addition, GR-MD-02 was able to reverse the inflammatory component of NASH (fat accumulation, liver cell degeneration and inflammatory cell infiltration). The ability of GR-MD-02 to reduce existing fibrosis is further supported by studies in toxin-induced fibrosis. Toxicology, pharmacology and manufacturing studies are currently being conducted to support submission of an IND application to the FDA by the end of 2012. A Phase 1 clinical trial in patients with NASH with advanced fibrosis is anticipated to begin in the first quarter of 2013.

About NASH

NASH is a common disease of the liver, affecting 9 to 15 million people in the United States and 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, that can lead to cirrhosis, a severe liver disease where transplantation is the only current treatment available. Galectin Therapeutics is developing drug candidates as an alternative to transplantation and lead candidates have reversed fibrosis in preclinical disease models.

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. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others: incurrence of operating losses since our inception, uncertainty as to adequate financing of our operations, extensive and costly regulatory oversight that could restrict or prevent product commercialization, inability to achieve commercial product acceptance, inability to protect our intellectual property, dependence on strategic partnerships, product competition, and others stated in risk factors contained in our SEC filings. We cannot assure that we have identified all risks or that others may emerge which we do not anticipate. 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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