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Galectin Therapeutics Engages PPD to Conduct GR-MD-02 Phase 2 Trial in NASH, Submits Special Protocol Assessment to FDA

Study Enrollment to Begin in the Second Quarter

NORCROSS, Ga., March 12, 2015 (GLOBE NEWSWIRE) -- Galectin Therapeutics (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announces it has engaged the contract research organization Pharmaceutical Product Development, LLC (PPD) to conduct the Phase 2 trial with GR-MD-02 for the treatment of liver fibrosis and resultant portal hypertension in patients with non-alcoholic steatohepatitis (NASH) cirrhosis (the NASH-CX trial). Galectin also announces it has submitted the protocol for a Special Protocol Assessment (SPA) to the U.S. Food and Drug Administration (FDA) with the goal of accepting the NASH-CX results, if positive, as one of the trials to support approval of the drug candidate.

"We are very pleased to have finalized our engagement of PPD, one of the leading contract research organizations in the world, and are excited to take this step toward the beginning of our Phase 2 program," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. "PPD's extensive experience in conducting clinical trials in liver-related diseases will serve us well. We are particularly attracted to their work with clinical trial sites possessing familiarity with hepatic venous pressure gradient (HVPG), as the FDA has indicated that HVPG may serve as a surrogate primary endpoint for NASH cirrhosis. We look forward to the prospect of bringing this new drug to the millions of people in the U.S. with NASH."

As previously announced, Galectin's Phase 2 program for GR-MD-02 currently consists of two clinical trials. The NASH-CX trial is designed as a multicenter, randomized, placebo-controlled, double-blind, parallel-group study with 156 patients at up to 60 sites to evaluate the safety and efficacy of GR-MD-02 for the treatment of liver fibrosis and resultant portal hypertension in NASH patients with cirrhosis. Enrollment is expected to commence in the second quarter of 2015, and data readout is expected in the fourth quarter of 2017. In addition, the Company will conduct a smaller trial of shorter duration in 30 NASH patients with advanced fibrosis (the NASH-FX trial). This randomized, placebo-controlled, blinded study will be conducted at Brooke Army Medical Center with enrollment expected to begin in mid-2015 and top-line data readout in mid-2016. In this study, the safety and efficacy of GR-MD-02 on liver stiffness will be evaluated by magnetic resonance-elastography and FibroScan score, and by imaging liver fibrosis using multi-parametric magnetic resonance imaging (LiverMultiScan®, Perspectum Diagnostics).

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 Fatty Liver Disease with Advanced Fibrosis and Cirrhosis

Non-alcoholic steatohepatitis (NASH), also known as fatty liver disease, has become a common disease of the liver with the rise in obesity rates. NASH is estimated to affect up to 28 million people in the U.S. Fatty liver disease is characterized by the presence of fat in the liver along with inflammation and damage in people who consume little or no alcohol. Over time, patients with fatty liver disease can develop fibrosis, or scarring of the liver, and it is estimated that as many as 1-2 million individuals in the U.S. will develop cirrhosis, a severe liver disease for which liver transplantation is the only treatment available. Approximately 6,300 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis.

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. There is no certainty that FDA and Company will agree on a SPA or that a SPA would ultimately be acceptable to FDA nor result in approval of GR-MD-02. 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, 2013, 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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