Galectin Therapeutics Proceeds to Phase 3 Development of GR-MD-02 for NASH Cirrhosis Following FDA Meeting

May 14, 2018

NORCROSS, Ga., May 14, 2018 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, announced today it is proceeding with plans for a Phase 3 clinical trial program with its galectin-3 inhibitor GR-MD-02 in NASH cirrhosis, incorporating advice and guidance obtained in a meeting with the US Food and Drug Administration (FDA).

The target population of the Phase 3 clinical trial will be patients with NASH cirrhosis without esophageal varices. The primary endpoint will be chosen from two endpoints that the FDA agreed may be acceptable: The change in hepatic venous pressure gradient (HVPG), which is a measure of liver blood pressure, or the progression to esophageal varices. Both primary endpoints may be considered surrogate endpoints for clinical outcomes in the target population with NASH cirrhosis. Details of the Phase 3 clinical trial design, including projected timings and costs, will be announced once the planning phase has been completed and the company has a final clinical trial protocol that is acceptable to the FDA.

“Planning for a Phase 3 development program represents a significant milestone for Galectin Therapeutics and a pathway forward for the development of GR-MD-02 as a potentially important therapy in patients with NASH cirrhosis,” said Dr. Peter G. Traber, M.D., CEO and CMO of Galectin Therapeutics. The basis for advancing to Phase 3 is the positive effects of GR-MD-02 on HVPG and the possible prevention or postponement of development of esophageal varices in the Phase 2 NASH-CX trial, which we believe is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in these patients. The potential choice between two primary endpoints for Phase 3 trials provides enhanced flexibility in designing the strongest trial to replicate the efficacy demonstrated in the Phase 2 NASH-CX trial. Additionally, the clinical trial design discussed with the FDA provides for interim analysis which may provide confirmation of Phase 2 results and enhanced confidence for the ultimate results of the Phase 3 trial.

“While the company believes the results of the Phase 2 NASH-CX trial may represent a breakthrough for patients with NASH cirrhosis and believes that the results meet the FDA requirements for Breakthrough Therapy designation, the FDA has not granted breakthrough designation at this time based on the Agency’s current assessment that additional confirmatory data are needed to identify the level of change in HVPG that is reasonably likely to predict clinical outcomes. Although we disagree with FDA’s decision not to grant Breakthrough Therapy designation at this time, we understand their position because our NASH-CX trial is to our knowledge indeed the first randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in HVPG in NASH cirrhosis patients. Importantly, the Phase 3 program will not be impeded by the lack of Breakthrough Designation at this time. The program continues to benefit from Fast Track designation which provides many of the same advantages as Breakthrough Therapy designation, including potential for accelerated approval and priority review.”

About NASH Cirrhosis
NASH cirrhosis is the final stage in the progression of non-alcoholic steatohepatitis (NASH), a disease of the liver which affects millions of people in the U.S. and worldwide. The liver cell death and inflammation seen in NASH eventually causes progressive scarring of the liver, which eventually can result in liver cirrhosis. While the early stages of NASH can be treated by changes in lifestyle, such as losing weight and exercising, once the disease progresses to NASH cirrhosis there is no treatment available short of a liver transplant. Of the total number of individuals in the world felt to presently have NASH, it is predicted that NASH cirrhosis will eventually kill 20 million of those people.

One of the results of NASH cirrhosis is an increase in blood pressure in the portal vein that brings blood and nutrients from the digestive tract through the liver and then out to the rest of the body. As the scarring effect of cirrhosis on the liver progresses, blood flow through the liver becomes more difficult, increasing the blood pressure in the portal vein, creating varying degrees of portal hypertension. Eventually, this increase in blood pressure causes the veins connected to the liver to dilate and form esophageal varices, which are dilated veins that divert blood through the esophagus, bypassing flow through the liver. These dilated veins in the esophagus are prone to bleeding, which is a major cause of morbidity and mortality in patients with NASH cirrhosis. About half of the patients with well compensated NASH cirrhosis do not have varices and identification of these patients is determined by endoscopy which is included in the standard of care for all patients with cirrhosis.

About the NASH-CX Trial
The NASH-CX trial was a randomized, double-blind, placebo-controlled Phase 2b clinical trial which enrolled 162 NASH cirrhosis patients; NASH-cirrhosis was confirmed both by liver biopsy and by confirmation of an elevated hepatic venous pressure gradient (HVPG). Enrolled patients received either 2 mg/kg or 8 mg/kg of GR-MD-02 or placebo every other week for 52 weeks, for a total of 26 doses. The aim of the NASH-CX clinical trial was to evaluate the safety and efficacy of GR-MD-02 in patients with well-compensated NASH cirrhosis. The primary study endpoint was a reduction in HVPG. Patients treated with GR-MD-02 were evaluated to determine the change in HVPG as compared to patients treated with placebo. Secondary end-points include NASH fibrosis stage and percent of fibrotic tissue based on liver biopsy and other non-invasive measures (see: www.clinicaltrials.gov for further details).

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 scarring of organs including fibrotic disorders of the liver, lung, kidney, heart and vascular system. The drug binds to galectin-3 proteins and disrupts its function. Preclinical data in animals have shown that GR-MD-02 has robust treatment effects in reversing liver fibrosis/cirrhosis and reducing portal hypertension in cirrhosis.

About Galectin Therapeutics
Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver disease, as well as other diseases related to increased expression of galectin-3 including inflammatory skin diseases and cancer. Galectin's lead drug (GR-MD-02) is a carbohydrate-based drug that inhibits the galectin-3 protein that is directly involved in multiple inflammatory, fibrotic, and malignant diseases. The lead

development program is in non-alcoholic steatohepatitis (NASH) with cirrhosis, the most advanced form of NASH related fibrosis. This is the most common liver disease and is believed to be one of the largest drug development opportunities available today. Additional development programs are for treatment of severe atopic dermatitis, moderate-to-severe plaque psoriasis, and in combination immunotherapy for advanced melanoma and other malignancies. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. 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,” “possibly,” “possible,” “believe,” “could,” “potential,” “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 and those regarding the hope that our lead compounds will be successful in the treatment of severe atopic dermatitis, moderate-to-severe plaque psoriasis and in cancer immunotherapy. 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 anticipated Phase 3 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; 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, 2017, 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.

Investor Contact:
Galectin Therapeutics, Inc.
Jack Callicutt, Chief Financial Officer

Media Contact:
Gregory FCA
Leigh Minnier, Vice President
610-228-2108
leigh@gregoryfca.com

Source: Galectin Therapeutics Inc.