Galectin Therapeutics to Present Late-Breaker Oral Presentation at The International Liver Congress 2018

April 4, 2018

GR-MD-02 treatment in NASH cirrhosis patients without esophageal varices shows statistically significant and clinically meaningful effects

NORCROSS, Ga., April 04, 2018 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, announced today the presentation of a late-breaker oral presentation on Saturday April 14, 2018 at 16:00 CET in the Main Plenary at The International Liver Congress™ 2018, European Association for the Study of the Liver (EASL) in Paris, France.

Naga P. Chalasani, M.D., Associate Dean for Clinical Research; Director, Division of Gastroenterology and Hepatology at Indiana University School of Medicine; and co-lead principal investigators on Galectin Therapeutics' recent Phase 2b NASH-CX trial, will give an oral presentation during a late breaker session, entitled "A multicenter, randomized, double-blind, PLB-controlled trial of Galectin-3 inhibitor (GR-MD-02) in patients with NASH cirrhosis and portal hypertension." The session will focus on the Company's recent Phase 2b NASH-CX trial results and the innovative work it is doing for patients with non-alcoholic steatohepatitis (NASH) cirrhosis and portal hypertension.

The NASH-CX demonstrated statistically significant and clinically relevant positive effects of GR-MD-02 on portal pressure (hepatic venous pressure gradient or HVPG) and liver biopsy parameters in patients with NASH cirrhosis without esophageal varices following one year of therapy. Patients without esophageal varices comprise about 50 percent of the total population of patients with NASH cirrhosis. Such patients are readily diagnosed by endoscopy, which is already part of the standard of care for patients with suspected NASH. The drug was well tolerated during this one-year trial. The full details of the EASL presentation will be released on Monday, April 16, 2018.

"For NASH cirrhosis patients, there currently is no therapy. We believe this to be the first trial of its nature to demonstrate statistically significant and clinically meaningful improvements for patients with NASH cirrhosis without varices," said Dr. Peter Traber, CEO and Chief Medical Officer of Galectin Therapeutics. "We are pleased that Dr. Chalasani will present the results in a prominent session at the International Liver Congress".

The International Liver Congress 2018 is the premier annual international liver research conference. Hosted by EASL in April, the conference features scientific and medical experts from a broad range of fields including hepatology, gastroenterology, internal medicine, cell biology, transplant surgery, infectious diseases, microbiology and virology, pharmacology, pathology and more. Approximately 10,000 delegates and 250 media representatives attend annually.

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, in 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 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 8 mg/kg or 2 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 non-biologic 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 and cirrhosis.

About Galectin Therapeutics
Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver and 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 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.

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