Galectin Therapeutics Late-Breaker Presentation at The International Liver Congress Reinforces and Extends the Positive Effects of GR-MD-02 in Patients With NASH Cirrhosis

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

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 investigator on Galectin Therapeutics' recent Phase 2b NASH-CX trial, delivered a late-breaker presentation entitled "A multicenter, randomized, double-blind, PLB-controlled trial of Galectin-3 inhibitor (GR-MD-02) in patients with NASH cirrhosis and portal hypertension" (click for presentation). The session focused on the Company's recent Phase 2b NASH-CX trial results and the innovative work the Company is doing for patients with non-alcoholic steatohepatitis (NASH) cirrhosis and portal hypertension.

Dr. Chalasani's late-breaker presentation highlighted and extended the study's primary findings in patients without esophageal varices and those with mild portal hypertension. Most importantly, in patients with NASH cirrhosis without esophageal varices, Galectin Therapeutics' lead compound, GR-MD-02, demonstrated a statistically significant improvement in portal pressure, an improvement in liver cell death (hepatocyte ballooning) on biopsy for the total population, and a reduction in the development of new esophageal varices at the end of the one-year study. This subgroup is large and commercially relevant as it comprises about half of all patients with NASH cirrhosis.

Since reporting these initial findings in December 2017, continued analysis of the data has led to two additional findings that reinforce the positive effects of GR-MD-02. First, a statistically significant (p=0.04) correlation was identified between the decrease in portal pressure (HVPG, or hepatic venous pressure gradient) and the improvement in hepatocyte ballooning (viz., representing a decrease in liver cell death) upon treatment with GR-MD-02 at 2 mg/Kg. This suggests an important pathophysiological link between the improvement in liver biopsy and reductions in HVPG. To our knowledge, this is the first time that such a correlation has been demonstrated in a human clinical trial in patients with NASH cirrhosis.

Secondly, an evaluation of GR-MD-02 blood levels provided an explanation for the reduced efficacy response observed in the higher GR8 (8 mg/Kg) dose group. In the GR2 (2 mg/Kg) dose group, the blood levels (or total exposure to the drug as measured by area under the concentration-time curve) were tightly grouped. In contrast, there was a broad distribution of higher drug exposures in the GR8 group. Approximately half of the patients who received GR8 had GR-MD-02 blood concentration levels that had risen to a range where a reduced efficacy effect in the liver had been noted at very high doses in the NASH animal models.

When the GR8 group was divided, based on pharmacokinetic analysis of drug levels, into separate low (<12K µg*hr./mL) and high (>12K µg*hr./mL) drug exposure ranges, a statistically significant effect (p=0.03) of GR8 on both HVPG and hepatocyte ballooning was observed in those patients with drug levels in the lower drug exposure range. There was no corresponding statistically significant effect in the higher drug exposure range group of patients receiving GR8 in analogy to what was observed in the NASH animal studies. Therefore, the GR8 dose, in cirrhotic patients, seems to be at the upper range of efficacy. Importantly, this not only provides an explanation of the dose ranging results but also more clearly defines the upper range of human drug dosing for GR-MD-02 in patients with NASH cirrhosis. Further, these results suggest it might be useful to explore intermediate doses between 2mg/kg and 8mg/Kg in future clinical studies.

"The findings presented by Dr. Chalasani reinforce how the NASH-CX trial has demonstrated clinically meaningful improvement for those patients with NASH cirrhosis without esophageal varices with a drug that was well tolerated over one year of therapy," said Dr. Peter Traber, CEO and Chief Medical Officer of Galectin Therapeutics. "Since about 50 percent of the total population of patients with NASH cirrhosis do not have esophageal varices and endoscopy to evaluate for varices is part of the standard of care for patients with NASH cirrhosis, there is a large and easily identifiable population of patients that might benefit from GR-MD-02. We look forward to presenting our findings to the FDA next month and to continuing advanced clinical studies to progress GR-MD-02 toward approval for the treatment of NASH cirrhosis in an appropriate patient group."

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, that 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.

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 NASH with cirrhosis, and those regarding the hope that our lead compounds will be successful in connection with the treatment of skin disease and 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 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; the Company may find that its patents does not offer the protection anticipated, and 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.

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