Galectin Therapeutics Announces Results from Phase 2b NASH-CX Trial

December 5, 2017

Statistically significant and clinically meaningful effects observed in NASH cirrhosis patients without esophageal varices treated with GR-MD-02

Conference Call at 8:30 A.M. ET to Present Top Line Trial Results

NORCROSS, Ga., Dec. 05, 2017 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, announced today that its Phase 2b NASH-CX trial of its proprietary compound GR-MD-02 showed statistically significant and clinically meaningful results in reducing the primary endpoint measurement of HVPG (hepatic venous pressure gradient) in comparison to placebo in NASH cirrhosis patients without esophageal varices, which represented 50 percent of the patients enrolled in the clinical trial. There was a positive trend in the total group of patients (both with and without varices), but the difference did not reach statistical significance for this primary endpoint because there was more variability in HVPG measurements for patients with esophageal varices.

For the major secondary endpoint assessment of liver biopsy, analysis of the total study population (161 patients) showed a statistically significant effect of drug treatment for improving hepatocyte ballooning (liver cell death), which is a key factor in the underlying disease process in NASH. Importantly, analysis of the secondary endpoint of complications of cirrhosis showed there was a statistically significant reduction in the development of new esophageal varices in patients without varices at baseline.

We also performed a rigorous assessment of the response to therapy by evaluating the percent of patients who had a reduction of HVPG from baseline (Responder Analysis). Responders were defined as having reductions of HVPG from baseline that have been shown to be clinically significant, an absolute reduction of ≥ 2 mmHg of HVPG from baseline or a ≥ 20 percent reduction of HVPG from baseline. Based on reduction in absolute HVPG, patients without varices who received a 2 mg/kg dosage of GR-MD-02 showed a statistically significant greater percentage of responders than those without varices in the placebo group (44 percent versus 15 percent, p=0.02). The same statistically significant results were seen when responders were analyzed based on a ≥ 20 percent reduction from baseline HVPG (40 percent versus 15 percent, p=0.03).

“There is no current therapy for patients with NASH cirrhosis -- and a therapy such as GR-MD-02 that could improve portal hypertension and potentially prevent the development of esophageal varices in NASH cirrhosis and subsequent complications -- would be clinically valuable,” said Stephen A. Harrison, M.D., one of lead investigators of the NASH-CX trial, medical director of Pinnacle Clinical Research in San Antonio, Texas, and visiting professor of medicine at the University of Oxford, United Kingdom. “An indication of NASH cirrhosis without varices would be clinically meaningful to physicians, because it is standard of care for all patients with cirrhosis to have an upper endoscopy to assess for the presence of esophageal varices.”

“We believe this is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in portal hypertension or liver biopsy in patients with NASH cirrhosis without varices,” said Dr. Peter G. Traber, M.D., CEO and CMO of Galectin Therapeutics. “Furthermore, we believe that the results stratify a large and easily identifiable group of patients. The results also suggest several potential registration endpoints that may be employed in a phase 3 program, including absolute or percent changes in HVPG, the percentage of patients who respond with a clinically relevant reduction in HVPG (Responder Analysis), and the development of esophageal varices, which may be considered a clinical outcome by regulatory agencies. Additionally, we are gratified to note that the drug was also well tolerated, and no safety concerns were detected.

“We would like to express our gratitude to the NASH patients who participated in this trial and to their physicians. Their unwavering commitment, over the year-long course of therapy, allowed this trial to be completed in a timely manner, and their dedication to helping others find a treatment for NASH is most laudable.”

Galectin Therapeutics will hold a conference call at 8:30 a.m. Eastern today to discuss the trial results. Peter G. Traber, M.D., the company’s CEO and CMO, and Stephen A. Harrison, M.D., one of lead investigators of the NASH-CX trial, medical director of Pinnacle Clinical Research in San Antonio, Texas, and visiting professor of medicine at the University of Oxford, United Kingdom, will present the results in the webcast.

Dial-in information and webcast details are listed below:

Tuesday, December 5, 2017, 8:30 a.m. Eastern Time
Participant Toll Free Dial-In Number: 888-317-6003
Participant International Dial-In Number: 412-317-6061
Conference ID: 3493752
Webcast URL:
https://services.choruscall.com/links/galt171205.html

Dial-in information and webcast details for replay access are listed below. The dial-in replay will be available until Tuesday, Dec 12, 2017. The webcast replay will be archived for one year.

Replay Toll Free Dial-In Number: 877-344-7529
Replay International Dial-In Number: 412-317-0088
Replay Access Code: 10114808
Webcast Replay:
https://services.choruscall.com/links/galt171205.html

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 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, 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 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.
These statements include those regarding the potential therapeutic benefits of our drugs and specifically the results of our NASH-CX clinical trial. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others that:

- the data presented today represent a top line analysis, and there may be changes in the final clinical trial report due to further analysis of the full data set including additional statistical analysis;
- subsequent trials, if any, in whatever patient population chosen may fail to validate any positive results of our trial now concluded;
- future phases or future clinical studies could prove prohibitively time consuming and/or costly;
- plans regarding development, approval and marketing of any of our drugs are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies;
- strategies, personnel, and spending projections may change;
- due to the novel nature of our compounds, future phases of manufacturing scale-up and supporting chemical and physical characterizations for both trials and commercial purposes can be challenging and costly and there is no certainty this can be accomplished nor certainty it would acceptable to regulators;
- we may be unsuccessful in developing partnerships or other business relationships with other companies or obtaining capital that would allow us to further develop and/or fund any future studies or trials or sell or license our intellectual property; and, further,
- there is the uncertainty that any drug in development could obtain regulatory approval in any patient population.

To date, we have incurred operating losses since our inception, and our future success may be impacted by our ability to manage costs and finance our continuing operations. For a discussion of additional factors impacting our business, see our Annual Report on Form 10-K for the year ended December 31, 2016, and our subsequent filings with the SEC. 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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