Galectin Therapeutics Announces 2 Liver Cirrhosis Scientific Presentations at the EASL International Liver Congress™ 2022

June 21, 2022

NORCROSS, Ga., June 21, 2022 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin-3, announced today two scientific presentations regarding the use of artificial intelligence to analyze liver biopsies of patients affected with cirrhosis of the liver due to Nonalcoholic Steatohepatitis (NASH). The data originates from the Company's phase 2 study (NCT02462967) that evaluated its proprietary drug candidate belapectin in patients with NASH cirrhosis who have developed portal hypertension. Portal hypertension is a severe clinical complication of the disease that marks a significant progression towards liver failure and for which, currently, no treatment is registered. The presentations will be delivered by Dr. Mazen Noureddin of the Division of Digestive and Liver Diseases, Comprehensive Transplant Center, Cedars-Sinai Medical Center, Los Angeles, CA, United States, during the International Liver Congress™ 2022 hosted by the European Association for the Study of the Liver (EASL) on June 22-26, 2022 in London, U.K.

The first abstract (FRI509) focuses on the use of second-harmonic generation microscopy for automated detection of septa and nodules in liver biopsies of NASH cirrhosis patients. As current staging systems oversimplify all degrees of cirrhosis into one category, artificial intelligence can be used to develop more sophisticated algorithms to correlate with the natural history of the disease, including the development of portal hypertension.

The second abstract (FRI 516) focuses on derivation of machine learning histologic scores that correlate with portal pressures and the development of esophageal varices. Esophageal varices represent a severe clinical complication of portal hypertension, as they can bleed and, consequently, be immediately life-threatening. The Machine Learning algorithm used could predict the degree of portal hypertension and the development of varices in patients with portal hypertension.

Dr Pol Boudes, Chief Medical Officer of Galectin Therapeutics commented: "Galectin Therapeutics has accumulated significant clinical development expertise in liver cirrhosis and the management of portal hypertension, which represents one of the most significant clinical complications of the disease. This field has been neglected by drug developers for far too long, and we are happy to share these data with the medical community through our collaboration with our investigators and HistoIndex Pte Ltd." Dr Boudes added: "Liver biopsies are particularly difficult to interpret in patients with NASH but, even more so, in patients with NASH cirrhosis. In cirrhosis, key elements such as the nodular structure of the liver and the nature of collagen septa are not amenable to interpretation with the currently available technologies. Also, patients with portal hypertension frequently have abnormally low platelet counts and liver biopsies are dangerous due to a significant increased risk of severe bleeding. Thus, biopsies may have to be performed with an intravenous access through a jugular vein. This is a complex procedure that also provides limited amount of liver tissue compared to a trans-cutaneous biopsy. The HistoIndex technology is very interesting because it allows the analysis of biopsy tissue without having to rely on staining of slides, the quality of which can impact results and increase variability."

About Belapectin

Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH 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. Belapectin binds to galectin-3 and disrupts its function. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis. A Phase 2 study showed belapectin may prevent the development of esophageal varices in NASH cirrhosis, and these results provide the basis for the conduct of the NAVIGATE trial. The NAVIGATE trial (www.NAVIGATEnash.com), titled "A Seamless Adaptive Phase 2b/3, Double-Blind, Randomized, Placebo-controlled Multicenter, International Study Evaluating the Efficacy and Safety of Belapectin (GR-MD-02) for the Prevention of Esophageal Varices in NASH Cirrhosis," began enrolling patients in June 2020, and is posted on www.clinicaltrials.gov (NCT04365868). Galectin-3 has a significant role in cancer, and the Company has supported a Phase 1b study in combined immunotherapy of belapectin and KEYTRUDA in advanced melanoma and in head and neck cancer. This trial provided a strong rationale for moving forward into a Company-sponsored Phase 2 development program, which the company is exploring.

About Fatty Liver Disease with Advanced Fibrosis and Cirrhosis

Non-alcoholic steatohepatitis (NASH) has become a common disease of the liver with the rise in obesity and other metabolic diseases. NASH is estimated to affect up to 28 million people in the U.S. It is characterized by the presence of excess fat in the liver along with inflammation and hepatocyte damage (ballooning) in people who consume little or no alcohol. Over time, patients with NASH can develop excessive fibrosis, or scarring of the liver, and ultimately liver cirrhosis. It is estimated that as many as 1 to 2 million individuals in the U.S. will develop cirrhosis as a result of NASH, for which liver transplantation is the only curative treatment available. Approximately 9,000 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis or cirrhosis.

About Galectin Therapeutics

Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver disease and cancer. Galectin's lead drug belapectin (formerly known as GR-MD-02) is a carbohydrate-based drug that inhibits the galectin-3 protein which is directly involved in multiple inflammatory, fibrotic, and malignant diseases, for which it has Fast Track designation by the U.S. Food and Drug Administration. 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 in treatment of combination immunotherapy for advanced melanoma and other malignancies. Advancement of these additional clinical programs is largely dependent on finding a suitable partner. 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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