Galectin Therapeutics' Statement Following the Recent 2023 Emerging Topic Conference on NASH Cirrhosis, Sponsored by the American Association for the Study of Liver Diseases

April 18, 2023

NORCROSS, Ga., April 18, 2023 (GLOBE NEWSWIRE) -- Galectin Therapeutics, Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, attended the *2023 Emerging Topic Conference on NASH Cirrhosis: From Mechanisms to Management*, sponsored by the American Association for the Study of Liver Diseases (AASLD). The Conference took place in Los Angeles, March 25-26, 2023.

The AASLD has created a new forum to share knowledge around NASH cirrhosis and explore current and future opportunities for patients affected with this devastating disease. Currently, the only curative treatment for patients is a liver transplantation, an expensive procedure whose access is extraordinarily limited. The conference was attended by members of the AASLD Hepatology Community who have a special interest in liver cirrhosis due to nonalcoholic steatohepatitis (NASH). The disease is projected to become a major global health issue, and the main reason for liver transplantation in the United States.

The conference was attended, moderated, and chaired by clinical investigators who have enrolled their patients in Galectin Therapeutics' ongoing NAVIGATE study, an innovative phase 2b/3 study evaluating the effect of belapectin for the primary prevention of esophageal varices in patients with portal hypertension due to NASH cirrhosis.

The conference notably highlighted the importance of understanding and targeting liver macrophages to slow the disease process. Belapectin, Galectin Therapeutics' candidate drug, is a galectin-3 inhibitor that targets macrophages, the main producer of this pro-inflammatory and pro-fibrotic molecule. There were also sessions dedicated to therapeutic targets and clinical study design. In the sessions on study designs the conferees addressed the choice of primary outcome of efficacy as well as the type of population that can be selected for registration drug candidates.

The conference reiterated the known limitation of liver biopsy, including the lack of sensitivity for response criteria in cirrhotic patients and the difficulty predicting the timing of cirrhotic decompensation events. While non-invasive biomarkers may offer opportunities in the future, more data must be gathered before considering them as potential surrogate markers of efficacy. In this context, the evaluation and prevention of esophageal varices, the primary outcome of efficacy of NAVIGATE, was highlighted as an interesting clinical option that could address the deficiency of other methods.

Dr. Pol Boudes, Galectin Therapeutics Chief Medical Officer, stated: "For far too long, liver cirrhosis has been a neglected disease for drug developers, and we welcome the organization of this conference by the AASLD. We are already facing a major crisis of patients afflicted with NASH cirrhosis, and future numbers are only projected to increase. If these projections are accurate, the health system will be completely overwhelmed. In the U.S., the shortage of transplants will be dramatic, and the cost of liver transplantations to society will lead to further rationing. The situation is already dramatic and will grow even worse in countries that have limited or no possibility of liver transplants."

Dr. Boudes added: "While the conference highlighted the current limitations of classical study designs (liver histology in early-stage cirrhosis, decompensation events in late-stage cirrhosis), I am optimistic that NAVIGATE's design offers a way forward for patients. The evaluation of patients at the non-decompensated portal hypertension stage, which is an intermediary stage between early-stage cirrhosis and decompensated cirrhosis, and the primary prevention of esophageal varices, a clinical endpoint, offer a realistic way forward for patients. Currently, Galectin Therapeutics is the only company using this clinical development strategy. While non-invasive biomarkers may offer a possibility to simplify drug development in the future, if they can be used as surrogate markers of clinical outcome, patients cannot wait. Acceleration of drug development for NASH cirrhosis right now is critically important."

About Galectin Therapeutics

Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with liver cirrhosis and cancer. Galectin's lead drug belapectin (formerly known as GR-MD-02) is a carbohydrate-based drug that inhibits galectin-3, a protein which is directly involved in multiple inflammatory, fibrotic, and malignant processes. Belapectin has received a Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of NASH cirrhosis. Belapectin's lead development program is liver cirrhosis due to non-alcoholic steatohepatitis (NASH). Liver cirrhosis is the most advanced form of NASH, a disease that, at this stage, is understood not to be reversible by any metabolic intervention, and, short of liver transplantation, is not amenable to specific therapeutic intervention. The number of patients with NASH cirrhosis is projected to grow exponentially and to become the most common form of liver cirrhosis. As a result, new therapeutic options are urgently needed. An additional development program of belapectin is in treatment of combination immunotherapy for advanced Head and Neck Cancers, and an Investigational New Drug (IND) has been filed with the FDA. Advancement of this additional clinical program 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**.

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," completed randomization of 357 patients in February 2023 with top-line data expected from the Phase 2b portion in the fourth quarter of 2024, 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), also known as fatty liver disease, 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.

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 belapectin 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 cancer immunotherapy and in other therapeutic indications. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that trial endpoints required by the FDA may not be achieved; Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of belapectin or any of its other drugs in development; the Company may not be successful in scaling up manufacturing and meeting requirements related to chemistry, manufacturing and control matters; the Company’s current clinical trial and any future clinical studies as modified to meet the requirements of the FDA may not produce positive results in a timely fashion, if at all, and could require larger and longer trials, which would be 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. Global factors such as coronavirus may continue to impact NASH patient populations around the globe and slow trial enrollment and prolong the duration of the trial and significantly impact associated costs. 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, 2022, 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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