Galectin Therapeutics Reports the Positive Outcome of the First Data and Safety Monitoring Board for NAVIGATE, its Seamless, Adaptive Phase 2b/3 Study of Belapectin in Patients with Liver Cirrhosis Caused by Non-Alcoholic Steatohepatitis

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NORCROSS, Ga., April 14, 2022 (GLOBE NEWSWIRE) -- Galectin Therapeutics, Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin-3, today reported the positive outcome of its first data and safety monitoring board (DSMB) meeting for NAVIGATE, its seamless, adaptive, phase 2b/3 study of belapectin in patients with liver cirrhosis caused by non-alcoholic steatohepatitis (NASH). NAVIGATE is the first study of its kind and is a global effort that recruits patients over 15 countries and five continents. The study main efficacy objective is the primary prevention of esophageal varices. Patients enrolled in the study have liver cirrhosis caused by NASH and, because of the advancing cirrhotic process, have already developed portal hypertension but have not yet developed esophageal varices as a complication of portal hypertension. Portal hypertension is the consequence of the unrelented inflammatory and fibrotic process occurring in the liver and dramatically increases the risk of developing esophageal varices, a potentially life-threatening complication of liver cirrhosis.

The objective of this first independent DSMB was to review the emerging tolerance and safety profiles of belapectin. Based on its deliberation, the DSMB concluded that NAVIGATE can continue as designed, without modifications.

Dr. Pol Boudes, M.D., Chief Medical Officer of Galectin Therapeutics, said: “The positive recommendation of the DSMB meeting is a very important milestone for Galectin Therapeutics and for patients affected by liver cirrhosis due to NASH. This recommendation confirms that belapectin appears safe and well tolerated to date. Such a safety profile is an essential asset for a candidate drug designed for cirrhotic patients, as they are fragile, may need adjustment or interruption of common drug treatments, and are also frequently immune-compromised. Currently patients with decompensated liver disease, have no other hope than to receive a liver transplantation. A transplantation is a complex and expensive procedure, requiring life-long immunosuppression and specialized follow-up, and is further affected by a global shortage of organs. With the NASH epidemy and the resulting increasing number of patients that will suffer from liver cirrhosis, the liver organ shortage is only going to get worse, further highlighting the urgent need for new treatments. This successful DSMB meeting furthers our objective of advancing the belapectin program and bringing hope to our patients. I also want to take this opportunity to thank our investigators and their teams for participating in this innovative study.”

Dr. Boudes added: “The first patients in NAVIGATE have now reached their 18-month visit and have elected to continue into the extension phase of the phase 3 part of NAVIGATE. This is an additional significant milestone for the belapectin development program as we are now starting to collect follow-up data beyond a year and a half of treatment to further inform the benefit risk of belapectin in cirrhotic patients.”

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**.

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, 2021, 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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