Galectin Therapeutics Launches NAVIGATEnash.com, a Resource for Both Patients and Physicians about its Innovative NASH Cirrhosis Study

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Galectin Therapeutics is actively recruiting patients into NAVIGATE, its seamless, adaptive Phase 2b/3 study of belapectin for the prevention of esophageal varices in NASH cirrhosis

NORCROSS, Ga., April 06, 2021 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, today announced the launch of NAVIGATEnash.com, its dedicated trial website. The new website intends to educate patients and physicians about liver cirrhosis resulting from non-alcoholic steatohepatitis (NASH) as well as support NAVIGATE, the Company's innovative, seamless adaptive Phase 2b/3 study in NASH cirrhosis.

There is currently no treatment to stop the progression and more serious complications of NASH cirrhosis. The NAVIGATE Study is offering patients and their families an opportunity to contribute to the development of the first potential therapy targeted specifically at NASH cirrhosis and designed to improve clinical outcomes.

"Discussions in our broad community tend to focus on investment and intervention in early stages of NASH, with little attention given to patients who have progressed to NASH cirrhosis. However, since assuming my role in September, I have been moved by the determination of this overlooked patient community and the physicians who treat them. Both deserve dedication and investment in finding a meaningful treatment," said Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics. "NAVIGATEnash.com is not only meant to engage this important community – who may be looking to participate in NAVIGATE – and inform others about NASH cirrhosis, it is intended to send a message to a much broader community that we are willing to overcome the largest challenge in this space."

"NASH is quickly becoming the number one cause of liver cirrhosis. Unfortunately, the only treatment option for patients who progress to NASH cirrhosis is a liver transplant, something we, at Galectin Therapeutics, hope to change," said Pol F. Boudes M.D., Chief Medical Officer of Galectin Therapeutics. "We want to provide the necessary information to patients and physicians about our study, since, unlike other clinical trials in NASH, NAVIGATE specifically targets the prevention of a potentially life-threatening manifestation of NASH cirrhosis."

NAVIGATEnash.com is designed to educate patients, their families, and friends on the causes and potential complications of NASH cirrhosis. The site provides resources for additional information, details about NAVIGATE, and how, potentially, to participate. A "For Physicians" section provides physicians information on NASH cirrhosis and guidance on whether participating or referring patients to NAVIGATE might be appropriate.

The goal of the NAVIGATE Study is to prevent the development of esophageal varices, thought to be an early sign of more serious complications of NASH cirrhosis. Bleeding esophageal varices are a cause of death in about one-third of cirrhotic patients. An earlier clinical trial showed that belapectin, a galectin-3 inhibitor, may prevent the development of esophageal varices in patients with compensated NASH cirrhosis and was well tolerated and appeared safe.

About NASH Cirrhosis

NASH cirrhosis is the end stage of non-alcoholic steatohepatitis (NASH), which is characterized by the presence of excess fat in the liver. Over time, scar tissue and regenerative nodules resulting from the inflammation and fibrosis of NASH replace healthy liver tissue, preventing the liver from functioning normally. Over 28 million people in the U.S. are thought to suffer from NASH, and an estimated 1 to 2 million of them will eventually progress to NASH cirrhosis. NASH cirrhosis will soon become the number one reason for liver transplants.

About Belapectin (GR-MD-02)

Belapectin (GR-MD-02) 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. Galectin-3 also has a significant role in cancer, and the Company is supporting a Phase 1 study in combined immunotherapy of belapectin and Keytruda® in treatment of advanced melanoma and in head and neck cancer.

About the NAVIGATE Study

The NAVIGATE Study (originally named the NASH-RX trial) is an international, seamless, adaptively-designed Phase 2b/3 trial of the galectin-3 inhibitor belapectin (GR-MD-02), the company's lead compound, in NASH cirrhosis patients who have clinical signs of portal hypertension and are at risk of developing esophageal varices. Belapectin had previously been shown that it could prevent the development of new varices in this patient population. The NAVIGATE Study is expected to enroll approximately 315 NASH patients in the Phase 2b part of the trial at approximately 130 sites in 12 countries in North America, Europe, Asia and Australia. After 18 months of treatment, an interim analysis will be conducted to determine the optimum dosage of belapectin, and the NAVIGATE Study will move into Phase 3 with additional patients for another 18 months of treatment.

More information on the NAVIGATE Study can be found at NAVIGATEnash.com.

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 NAVIGATE 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 COVID-19 may limit access to NASH patient populations around the globe and slow trial enrollment and prolong the duration of the trial and significantly impact associated costs as well as impact other trial related activities including, amongst others, manufacturing and regulatory reviews. 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, 2020, 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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