



Galectin Therapeutics Reports the Positive Outcome of the Fourth Data and Safety Monitoring Board Meeting for NAVIGATE, its Seamless, Adaptive Phase 2b/3 Study of Belapectin in Patients with Portal Hypertension Caused by Non-Alcoholic SteatoHepatitis Live

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NORCROSS, Ga., Oct. 03, 2023 (GLOBE NEWSWIRE) -- [Galectin Therapeutics, Inc.](#) (NASDAQ: GALT), the leading developer of therapeutics that target galectin-3, today reported the positive outcome of its fourth data and safety monitoring board (DSMB) meeting for NAVIGATE, its seamless, adaptive, Phase 2b/3 study of belapectin in patients with portal hypertension caused by non-alcoholic steatohepatitis (NASH) liver cirrhosis. NAVIGATE is the first study of its kind and is a global effort that randomized 357 patients in 14 countries on five continents. The main efficacy objective is the primary prevention of esophageal varices. Interim topline data from the Phase 2b portion of NAVIGATE is expected in the fourth quarter of 2024.

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 unrelenting 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 fourth independent DSMB was to further review the emerging tolerance and safety profiles of belapectin. Based on its deliberation, which included an unblinded review of the data collected thus far, the DSMB concluded that NAVIGATE can continue as designed, without modifications.

Dr. Pol Boudes, M.D., Chief Medical Officer of Galectin Therapeutics, said: "The fourth positive recommendation of the DSMB meeting is another essential milestone for Galectin Therapeutics and its belapectin program, and for patients affected by liver cirrhosis caused by NASH (also known as Metabolic dysfunction-Associated SteatoHepatitis, or MASH). The study is fully randomized, and we are continuing to collect a large amount of safety data, including patients who have completed up to 36 months of treatment. This fourth recommendation further strengthens our confidence that belapectin can offer a beneficial risk-benefit profile. Because of the cirrhotic process and the multiple co-morbidities of the metabolic syndrome, such as hypertension, type 2 diabetes and obesity, NAVIGATE patients are generally on multiple medications and at risk of severe complications, including infectious events triggered by an immune deficient state. In this medically complex environment, a candidate drug designed for cirrhotic patients must be safe and well-tolerated. Currently, patients with decompensated liver cirrhosis have no hope other than to receive a liver transplantation. A liver transplantation is a complex and expensive procedure, requiring life-long immunosuppression and specialized follow-up, and is dramatically rationed by a global shortage of organs and a lack of access creating unwanted disparities throughout North America and the rest of the world. With the NASH/MASH epidemic 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. I again want to take this opportunity to thank patients and their families, investigators and their teams for participating in this innovative study, and the relentless efforts and commitment of the Galectin team."

About Belapectin

Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH/MASH 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," is fully enrolled, and further details are 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 liver cirrhosis due to NASH/MASH and portal hypertension

Non-alcoholic steatohepatitis (NASH), also known as MASH, 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. Liver cirrhosis is further complicated by portal hypertension which is one of the main mechanisms leading to decompensated 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/MASH, 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 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 galectin-3, a protein which is directly involved in multiple inflammatory, fibrotic, and malignant diseases processes. Belapectin received a Fast Track designation by the U.S. Food and Drug Administration. The lead development program is liver cirrhosis caused by non-alcoholic steatohepatitis (NASH), also known as Metabolic dysfunction-Associated SteatoHepatitis (MASH), the most advanced form of NASH/MASH-related fibrosis. An additional development program of belapectin is in combination with immunotherapy (checkpoint inhibitors) for advanced Head and Neck cancers. Advancement of this additional clinical programs is largely dependent on additional financing and/or 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, findings of safety of a drug candidate are not indicative of the drug candidate’s efficacy; 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 further 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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Galectin Therapeutics and its associated logo is a registered trademark of Galectin Therapeutics Inc. Belapectin is the USAN assigned name for Galectin Therapeutics’ galectin-3 inhibitor belapectin (GR-MD-02).