Galectin Therapeutics Announces Publication of NAVIGATE Phase 2b Trial Results for Belapectin in the Journal of Hepatology

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NORCROSS, Ga., May 11, 2026 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ:GALT), a clinical-stage biotechnology company developing therapeutics that target galectin-3 for patients with MASH cirrhosis and portal hypertension, today announced the publication of results from its NAVIGATE Phase 2b clinical trial evaluating belapectin in patients with MASH cirrhosis and portal hypertension in AASLD flagship journal Hepatology.

The manuscript, titled “Efficacy and Safety of Belapectin for the Prevention of Esophageal Varices in Patients with MASH Cirrhosis: The Randomized, Placebo-Controlled NAVIGATE Trial,” is now available online and available as an open-access publication.

The NAVIGATE trial evaluated belapectin, a galectin-3 inhibitor, in patients with MASH cirrhosis and portal hypertension without esophageal varices at baseline. Results demonstrated that belapectin 2 mg/kg was associated with a numerical reduction in the development of new varices compared to placebo in the full analysis set, with a statistically significant reduction observed in the per-protocol population. Key markers of fibrosis including Liver Stiffness Measure results were aligned with the clinical finding belapectinwas generally safe and well tolerated.

“These findings provide clinically meaningful evidence for the potential role of belapectin in addressing portal hypertension and reducing the risk of clinically significant complications in patients with MASH cirrhosis,” said Prof. Naga Chalasani, David W. Crabb Professor of Gastroenterology and Hepatology at Indiana University School of Medicine and principal investigator for the NAVIGATE program. “The observed reduction in variceal development, together with consistent biomarker findings and a favorable safety profile, supports continued development of belapectin in patients with MASH cirrhosis and portal hypertension—a population with substantial unmet medical need.”

“These results further strengthen the clinical and mechanistic profile of belapectin in MASH cirrhosis and portal hypertension,” said Khurram Jamil, M.D., Chief Medical Officer of Galectin Therapeutics. “The consistency across clinical outcomes and noninvasive biomarkers, including signals of reduced risk of clinically significant portal hypertension and variceal development, reinforces our confidence in belapectin’s potential to modify disease progression. We believe these data meaningfully support continued advancement of our program, while positioning belapectin as a differentiated therapeutic candidate in MASH cirrhosis with portal hypertension—a market with significant unmet need and limited treatment options.”

The manuscript highlights:

- Numerical reduction in incidence of new esophageal varices with belapectin 2 mg/kg compared to placebo
- Statistically significant reduction in the per-protocol population
- Supportive changes in non-invasive markers of portal hypertension and fibrosis including LSM and ELF.
- Favorable safety and tolerability profile

Belapectin targets galectin-3, a key mediator of fibrosis and inflammation, and is being developed as a potential therapy to address complications of MASH cirrhosis.

The full manuscript is available online and can be accessed here freely given its open-access status.

About NAVIGATE

NAVIGATE was a global, randomized, placebo-controlled Phase 2b trial evaluating belapectin in patients with MASH cirrhosis and portal hypertension without esophageal varices at baseline. The study assessed the development of varices and other clinically relevant outcomes over an 18-month treatment period.

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 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 metabolic dysfunction-associated steatohepatitis (MASH, formerly known as nonalcoholic steatohepatitis, or NASH) with cirrhosis, the most advanced form of MASH-related fibrosis. Liver cirrhosis is one of the most pressing medical need and a significant drug development opportunity. Additional development programs are in treatment of combination immunotherapy for advanced head and neck cancers 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”, “look forward”, “believe”, “hope” 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 MASH, formerly known as NASH, 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, full analysis of the NAVIGATE trial data may not product positive data; 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 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. 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, 2024, 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.

Company Contact:

Jack Callicutt, Chief Financial Officer
(678) 620-3186
ir@galectintherapeutics.com

Investors Relations Contacts:

Kevin Gardner
kgardner@lifesciadvisors.com

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.