Galectin Therapeutics Presented NAVIGATE Trial Results at the European Association for the Study of the Liver (EASL) 2025 Congress

05/12/25

- Data presentation included efficacy and biomarker analyses from the NAVIGATE trial (n=287).
- Belapectin 2 mg/kg demonstrated a statistically significant reduction in new varices at 18 months in the per-protocol population (p=0.04).
- Significantly fewer patients in the belapectin treatment arms experienced worsening of liver stiffness as measured by FibroScan®, reinforcing the potential beneficial effect of belapectin in halting the progression of MASH cirrhosis.

NORCROSS, Ga., May 12, 2025 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ:GALT), the leading developer of galectin-3-targeted therapeutics for patients with MASH cirrhosis and portal hypertension, presented a late-breaking oral presentation of the NAVIGATE study analysis at the EASL 2025 Congress, on May 10, 2025, in Amsterdam, Netherlands. The NAVIGATE study evaluated belapectin, a galectin-3 inhibitor, in patients with MASH cirrhosis and portal hypertension.

The NAVIGATE trial (NCT04365868) is a global, multicenter, randomized, double-blind, placebo-controlled study. A total of 355 patients were randomized in a 1:1:1 ratio to receive intravenous belapectin at either 2 mg/kg of lean body mass (LBM) (n=119), 4 mg/kg LBM (n=118), or placebo (n=118) every other week for 18 months. The primary endpoint was the prevention of varices, assessed as a composite clinical outcome that included patients who developed any varices, experienced intercurrent events, or lacked an endoscopy or intercurrent events at 18 months.

The study evaluated both the intent-to-treat (ITT) population (N=355) and a pre-defined per-protocol population or completer population (PPP, N=287), the latter comprising patients who completed 18 months of treatment with upper endoscopies performed at both baseline and after 18 months of treatment. In the PPP population, the incidence of varices was 11.3% in the belapectin 2 mg/kg group and 13.5% in the 4 mg/kg group, compared to 22.3% in the placebo group. The 2 mg/kg dose demonstrated a 49.3% reduction in incidence of new varices compared to placebo (p=0.04), whereas the 4 mg/kg dose showed a 39.5% reduction in new varices compared to placebo (not statistically significant).

These clinical findings were further supported by non-invasive assessments. Specifically, liver stiffness, measured via FibroScan®, showed a notably lower proportion of patients with worsening in liver stiffness. Notably, the 2mg/kg group significantly outperformed placebo by 66% (p=0.02) and 51% (p=0.03) respectively in each category as shown below:

	placebo	2 mg/kg belapectin	4mg/kg belapectin
	N=88	N=94	N=87
>10 increase in kPa from baseline Percentage	11 12.5%	4 4.3%	9 10.3%
>30% increase from baseline Percentage	21 23.9%	11 11.7%	13 14.9%

As in prior trials, the safety profile of belapectin remains highly encouraging with incidence of adverse events and serious adverse events comparable across the three cohorts. Rates of discontinuation, adverse events (AEs), and serious adverse events (SAEs) were comparable to placebo, with no drug-related SAEs reported in the NAVIGATE trial.

Dr. Naim Alkhouri, MD, FAASLD, DABOM, Chief Academic Officer of Summit Clinical Research and the Director of the Steatotic Liver Program at the Clinical Research Institute of Ohio, commented: "We are excited to have presented results from the NAVIGATE study, which reinforces belapectin's potential in addressing a significant unmet need in patients with MASH cirrhosis and clinically significant portal hypertension. Galectin Therapeutics was among the first to pursue prevention of esophageal varices as a clinical endpoint—an approach now gaining broader interest across the field. It's encouraging to see the consistency in benefit with the 2 mg dose in this global study."

Dr. Naga Chalasani, David W. Crabb Professor of Gastroenterology and Hepatology and Adjunct Professor of Anatomy, Cell Biology & Physiology at Indiana University School of Medicine, stated: "The NAVIGATE study contributes meaningful new evidence supporting belapectin's therapeutic potential in MASH cirrhosis. In addition to reducing varices development, the data show that fewer patients experienced worsening in liver stiffness measure by Fibroscan, a key biomarker of clinical outcomes. These liver stiffness thresholds are well established as being associated with poorer clinical outcomes, so this trend is particularly encouraging as the review of the full dataset continues. Belapectin clearly is showing benefit evidence across several clinically important endpoints and should be continued in clinical development as there is a significant unmet need for patients with MASH 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 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