Galectin Therapeutics Reports Significant Reduction in New Varices with Belapectin in U.S. Patient Population from the NAVIGATE Trial

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- **Additional analysis of data from the NAVIGATE trial showed statistically significant 68.1% (p=0.02) reduction in the incidence of new varices with belapectin vs placebo in per-protocol patients (completers) enrolled in the U.S.**
- **New estimates indicate around 3 million adults in the U.S. suffer from MASH cirrhosis and clinically significant portal hypertension[1], for which there are no FDA approved therapies**
- **Full analysis of the NAVIGATE trial is ongoing; additional data, including from patients completing 36 months of treatment, expected by end of Q1 2025**

NORCROSS, Ga., Feb. 18, 2025 (GLOBE NEWSWIRE) -- Galectin Therapeutics, Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today announced additional results showing a statistically significant reduction in new varices in per-protocol patients (completers) enrolled in the U.S. from the NAVIGATE trial for belapectin in patients with Metabolic Dysfunction-Associated SteatoHepatitis (MASH) cirrhosis and portal hypertension.

The NAVIGATE trial top-line results showed that while the incidence of varices at 18 months was 43.2% lower in patients treated with belapectin 2 mg vs placebo, the composite endpoint did not reach statistical significance in the intent-to-treat population (N=355). However, in the completer population of 287 patients (revised), the incidence of varices was reduced by 49.3% in patients treated with belapectin 2 mg vs placebo (nominal p-value = 0.04 (revised)).

Following the favorable trend observed in the completers, the Company further analyzed the two thirds of the completer patients in the NAVIGATE trial enrolled in the U.S. (n=186). The incidence of varices in this population was significantly reduced by 68.1% (p=0.02) in patients treated with belapectin 2 mg (4 out of 60) vs placebo (13 out of 62) in the U.S. While all three cohorts of patients in the U.S. had a higher percentage use of GLP-1 and statins than the rest of the world, the belapectin cohorts performed much better than placebo in the U.S.

Joel Lewis, Chief Executive Officer at Galectin Therapeutics commented: “With the prevalence of MASH cirrhosis and clinically significant portal hypertension in the U.S. now estimated in *Hepatology* at around 3 million adults, the need for new treatments that can prevent disease progression is more urgent than we had anticipated. The significant reduction of 68% we see in incidence of new varices in completer patients in the U.S. from the NAVIGATE trial underscores belapectin’s potential as a treatment for MASH cirrhosis and portal hypertension. We are continuing to analyze the data from the trial, including from the approximately 50 patients who completed 36-months of therapy. We look forward to sharing additional clinical updates as data becomes available in the first quarter of 2025.”

The Company will determine next steps for belapectin development with potential partners in conjunction with the completion of the ongoing analyses.

[1]Younossi ZM, de Avila L, Racila A, et al. Prevalence and predictors of cirrhosis and portal hypertension in the United States. *Hepatology*. 2025 Jan 29. doi: 10.1097/HEP.0000000000001243.

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 needs 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, 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 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, 2023, 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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