Galectin Therapeutics Provides Regulatory Update Following FDA Written Response and Announces an Additional $10 Million Line of Credit from Richard E. Uihlein Sufficient to Cover Expected Expenditures Through March 2027

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NORCROSS, Ga., Dec. 19, 2025 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ:GALT), the leading developer of galectin-3-targeted therapeutics for patients with MASH cirrhosis and portal hypertension, today announced that the U.S. Food and Drug Administration (FDA) has provided a written response, and subsequent communications, to the Company's previously submitted Type C meeting request regarding the development program for belapectin, its investigational galectin-3 inhibitor. The FDA converted the Company's initial request for an in-person or teleconference meeting to a written response.

Based on FDA's written feedback, the Company believes there is alignment with the Agency on the patient population proposed for enrollment in a registration trial. In addition, Galectin Therapeutics had previously reached an agreement with the FDA on the use of a centralized, blinded endoscopy review for esophageal variceal assessment and plans to apply a similar approach for variceal evaluation in its next study.

Pursuant to the written response from FDA, Galectin Therapeutics will pursue a follow-up Type C meeting to finalize remaining components of the next clinical trial design that were not fully resolved in the written response. This follow-up meeting will also provide an opportunity to present recently generated biomarker data, including findings highlighted at last month's American Association for the Study of Liver Diseases (AASLD) meeting, which could not be incorporated in the original submission due to our stated objective of obtaining FDA feedback before the end of 2025.

The Company views this next FDA interaction as an important step toward ensuring full clarity as it advances belapectin towards subsequent clinical development in a pivotal Phase 3 clinical trial. Galectin Therapeutics is also encouraged that the planned meeting will allow participation from prominent key opinion leaders, whose insights could not be integrated into the prior written-only exchange.

Galectin Therapeutics remains committed to advancing belapectin's development for patients with advanced fibrotic liver disease and continues to engage constructively with the FDA as it progresses the program.

Dr. Khurram Jamil, Chief Medical Officer at Galectin Therapeutics, stated, "We appreciate the FDA's written feedback and are encouraged by the agency's evolving consideration of non-invasive tools and surrogate markers into clinical development for MASH cirrhosis. We look forward to discussing our updated data set within that regulatory context and further refining the clinical development strategy for belapectin."

Separately, the Company has entered into a new $10 million unsecured, convertible line of credit financing agreement provided by its chairman, Richard E. Uihlein. In connection with this agreement, the maturity dates of all of the Company's convertible lines of credit and convertible notes payable to its chairman have been extended through June 30, 2027. The Company now believes that its cash resources, together with availability under these credit facilities, are sufficient to fund currently expected expenditures through at least March 2027.

Joel Lewis, Chief Executive Officer at Galectin Therapeutics, added, "Our focus remains on advancing belapectin for patients with MASH cirrhosis and portal hypertension. We were pleased to receive feedback prior to year-end and look forward to continued dialogue as we work to finalize the next stage of clinical development. The strength of the data generated to date reinforces our confidence in belapectin's potential, and we look forward to advancing this program with continued momentum. Finally, I would like to express our gratitude to Mr. Uihlein for once again increasing his commitment to the Company through the newest $10 million line of credit. This additional financing will enable us to continue to explore multiple strategies for the advancement of belapectin. We will provide updates as they become available."

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 the Company's cash resources and 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 produce 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