Galectin Therapeutics' Phase 2 NASH Cirrhosis Clinical Trial Results on Belapectin (GR-MD-02) Published in Gastroenterology

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NORCROSS, Ga., Dec. 09, 2019 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc.(NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, today announced that a paper highlighting the results of its NASH-CX Phase 2 clinical trial in NASH cirrhosis have been published in the peer-reviewed journal *Gastroenterology*. The paper, titled "Effects of Belapectin, an Inhibitor of Galectin-3, in Patients with Nonalcoholic Steatohepatitis with Cirrhosis and Portal Hypertension," was authored primarily by Naga Chalasani, M.D., of the Indiana University School of Medicine with the extensive support and assistance of many others.

Gastroenterology is the most prominent journal in the field of gastrointestinal disease. As the official journal of the AGA Institute, *Gastroenterology* delivers up-to-date and authoritative coverage of both basic and clinical gastroenterology. The paper is available now on the journal's website, gastrojournal.org, and will be included in an official issue of the journal at a later date.

The paper outlines that in a phase 2b study of 162 patients with NASH, cirrhosis, and portal hypertension, one year of biweekly infusion of belapectin was safe but not associated with significant reduction in HVPG or fibrosis, compared with placebo. However, in a subgroup analysis of patients without esophageal varices, 2 mg/kg belapectin (GR-MD-02) did reduce HVPG and development of varices. This subgroup analysis suggests that there may be benefits from belapectin in patients with NASH cirrhosis without esophageal varices. Further, if this observation can be reproduced in subsequent studies, belapectin may have a role in the management of patients with NASH cirrhosis and portal hypertension but no varices. Galectin Therapeutics is planning an adaptively-designed Phase 3 trial of belapectin in NASH cirrhosis patients as previously disclosed. A recent presentation is available on the Company's website.

"Our special thanks to Dr. Chalasani and his team, who wrote the paper with the help of Dr. Adam Allgood and others at Galectin, and assistance of the other authors," said Harold H. Shlevin, Ph.D., president and chief executive officer of Galectin Therapeutics.

"We are gratified that the results of the NASH-CX study and the quality of our science merited inclusion in a peer-reviewed journal of the caliber of *Gastroenterology*. The learnings from this Phase 2 study are being applied in the design of the Phase 3 trial," concluded Shlevin.

Galectin Therapeutics believes the NASH-CX trial is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in such patients.

About Belapectin (GR-MD-02)
Belapectin (also known as GR-MD-02) is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of fatty liver disease 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. The drug binds to galectin-3 proteins and disrupts its function. Belapectin is the first drug in a large, randomized clinical trial to demonstrate a clinically meaningful improvement in portal hypertension or liver biopsy in patients with NASH cirrhosis without varices. Galectin Therapeutics is undertaking a Phase 3 clinical trial in this patient population. Belapectin also has robust efficacy in pre-clinical cancer models in combination with immunotherapy agents; a Phase 1b extension to the cancer trial is currently underway.

About Galectin Therapeutics
Galectin Therapeutics is developing promising carbohydrate-based therapies for the treatment of fibrotic liver disease and cancer based on the Company's unique understanding of galectin proteins, which are key mediators of biologic function. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. The Company is pursuing a development pathway to clinical enhancement and commercialization for its lead compounds in liver fibrosis and cancer. 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 (GR-MD-02) will lead to the first therapy for the treatment of NASH with cirrhosis and those regarding the hope that our lead compounds will be successful in cancer immunotherapy. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, the Company's Phase 3 clinical trial for the treatment of NASH, now in the final planning stages, and any future clinical studies, including those in connection with cancer immunotherapy may not proceed and may not produce positive results in a timely fashion, if at all, and could prove 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; Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of belapectin; manufacturing of drug product now in scale-up may not be successful or meet regulatory expectations,; 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, 2018, 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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