



Galectin Therapeutics Reaches Agreement with Siemens Healthineers to Collaborate on NASH and Liver Fibrosis

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NORCROSS, Ga., Nov. 11, 2019 (GLOBE NEWSWIRE) -- Today, Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, announced a collaboration agreement with Siemens Healthineers, a global leader in medical technology, in nonalcoholic steatohepatitis (NASH) and liver fibrosis. This collaboration allows Siemens Healthineers to use Galectin's Phase 2 NASH-CX clinical trial to support regulatory filings of the ADVIA Centaur® Enhanced Liver Fibrosis (ELF)TM test.

This agreement will also provide Siemens Healthineers with access to future clinical and ADVIA Centaur ELF test data from Galectin Therapeutics' planned Phase 3 NASH-RX clinical trial of belapectin (GR-MD-02) in the treatment of NASH liver cirrhosis without esophageal varices.

"That a company the caliber of Siemens Healthineers wants to leverage the data from our clinical trials speaks to the scientific quality and relevance of our Phase 2 trial," said Harold Shlevin, Ph.D., president and CEO of Galectin Therapeutics. "While we are focused principally on the clinical development of our galectin-3 inhibitor to treat patients with NASH cirrhosis, we are pleased that our Phase 2 and future Phase 3 clinical data will otherwise help advance scientific research by providing data in support of a non-invasive test that offers the promise of monitoring progression and development of liver disease."

Siemens Healthineers was granted a Breakthrough Device designation for the ADVIA Centaur ELF test by the U.S. Food and Drug Administration (FDA) in 2018. The FDA's Breakthrough Devices program is intended to facilitate the development and expedite the review of breakthrough technologies to help patients gain more timely access to potentially effective treatment or diagnosis for life-threatening diseases for which no approved treatment exists.

If approved, the ADVIA Centaur ELF test, a simple blood test, would help clinicians better manage patients with chronic liver disease. The ELF test is designed to analyze results from three serum biomarkers, Hyaluronic acid (HA), Procollagen III amino-terminal peptide (PIIINP), and Tissue inhibitor of metalloproteinase 1 (TIMP-1), in an algorithm that provides a single unitless ELF score, which can help improve the prediction of NAFLD/NASH and chronic liver disease patients at risk of disease progression.¹

"At Siemens Healthineers, we are focused on improving the patient experience through less invasive testing procedures and expanding precision medicine through more personalized treatment decisions," said Dennis A. Gilbert, Ph.D., Head, Laboratory Diagnostics R&D. "Incorporating Galectin Therapeutics existing and future research will enhance our regulatory submissions for the clinical use of the ADVIA Centaur ELF test as a non-invasive tool in the management of patients with liver fibrosis, NAFLD, and NASH."

Currently, no similar blood test has been cleared or approved by FDA for clinical use in the United States.

ADVIA Centaur® is a registered mark of Siemens Healthcare Diagnostics Inc. Enhanced Liver Fibrosis (ELF)TM test is a trademark of Siemens Healthcare Diagnostics Inc.

¹Harrison SA, et al. AASLD 2017. Poster 2122.

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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