Galectin Therapeutics Plans Adaptively Designed Phase 3 NASH-RX Clinical Trial in NASH Cirrhosis

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Interim analysis after 12-18 months of treatment to reaffirm phase 2 results, select optimal dosage and sizing and seamlessly roll into Phase 3 stage of NASH-RX Study

Dr. Harold Shlevin, CEO, Discusses Plan at Annual Meeting of Stockholders

NORCROSS, Ga., Dec. 05, 2019 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, recently presented its current plans for an Adaptively Designed Phase 3 clinical trial (NASH-RX) of its lead compound, belapectin (GR-MD-02), in the treatment of patients with nonalcoholic steatohepatitis (NASH) cirrhosis without esophageal varices.

During a Corporate Update webcast held yesterday after the Company's annual stockholders meeting, president and chief executive officer Harold H. Shlevin, Ph.D., discussed the refinements the Company is making to its planned NASH-RX trial based on feedback from the U.S. Food and Drug Administration (FDA) from its most recent discussions with FDA on November 14, 2019. A recording of the webcast can be downloaded here. Additionally, Dr. Shlevin answered several questions posed by stockholders after the webcast, the transcript of which may be seen here.

"We are undertaking an Adaptively Designed trial that begins by confirming dose selection and the results observed in the NASH-CX trial," commented Dr. Shlevin. "An interim assessment of efficacy of belapectin, selection of an optimal dose and sizing will be conducted on an initial group of patients after 12-18 months of treatment, to seamlessly inform the progression to an integrated Phase 3 portion of trial. A Hepatic Impairment study will be conducted in parallel to allow potential inclusion of patients with more advanced cirrhosis in the trial. This approach allows us to optimize dosage, bolster the efficacy signal, and better size and power the later stages of the trial, increasing the potential likelihood of a successful Phase 3 trial."

The target population of the NASH-RX Phase 3 clinical trial is NASH cirrhosis patients with clinical signals suggesting portal hypertension who are at risk of developing esophageal varices. This is the population where belapectin demonstrated positive results in the earlier Phase 2 NASH-CX clinical trial. Patient selection for inclusion will be based on clinical criteria indicative of portal hypertension, including the presence or absence of varices, platelet count, spleen size, and evidence of collaterals by imaging. First patient enrollment is currently anticipated around the end of the first quarter in 2020. This is part of an overall program aimed at achieving accelerated approval via a surrogate endpoint. Additional information will be released as the trial plans progress.

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. 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 fatty liver disease with cirrhosis and those regarding the hope that our lead compounds will be successful in cancer immunotherapy and those related to newly discovered classes of small molecule inhibitors and future therapeutic uses of Galectin Sciences LLC. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that 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, the Company's NASH-RX clinical trial 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; 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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