Galectin Therapeutics Strengthens Leadership Team with Strategic Hires to Advance Programs in Cancer Immunotherapy and NASH Cirrhosis

August 30, 2021

NORCROSS, Ga., Aug. 30, 2021 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, today announced that the Company has recently expanded its management team with multiple key leadership appointments, including Dakshina Reddy, MSM, as Executive Director, Regulatory Affairs; Ezra R. Lowe, Ph.D., as Executive Director, Clinical and Preclinical Pharmacology; Marla Mills-Wilson as Executive Director, Clinical Operations; and Jessica Kopaczewski as Associate Director, Clinical Operations. These strategic appointments strengthen the company's clinical, regulatory, and operational efforts across its ongoing programs in cancer immunotherapy and NASH cirrhosis.

"The addition of these talented and experienced leaders to our team reflects another inflection point in our growth and development as we advance our exciting programs in NASH cirrhosis and cancer immunotherapy," said Joel Lewis, President and Chief Executive Officer of Galectin Therapeutics. "These hires, together with the recent appointment of Dr. Ben Carson, Sr., as Senior Advisor, demonstrate our commitment to building a world-class organization and a renewed culture focused on advancing our proprietary galectin-3 inhibitor to significant new milestones. These new team members bring valuable experience that will be instrumental at this critical point in our trials and other research. The Board of Directors and I share a vision for the potential of Galectin Therapeutics. I am grateful that the Board fully supports my goal in continuing to expand our team in these key areas of the organization, in order to achieve our next step in creating value for shareholders."

Dakshina Reddy
Executive Director, Regulatory Affairs

Dakshina Reddy has over 22 years of experience in regulatory affairs and clinical research. He has particular expertise in global regulatory, drug development and regulatory life-cycle management strategies, having worked with the FDA, EMA, PMDA and Health Canada amongst other leading regulatory agencies and emerging regulatory bodies in developing economies.

He most recently worked for Novartis as Global Program Regulatory Director, where he led and achieved successful approvals of IND's, NDA's, sNDA's and MAA's in the U.S., E.U., Japan, China, Brazil and Mexico.

Dakshina holds a Bachelor of Pharmacy from Rhodes University (South Africa) and a Master of Science Medicine (Pharmaceutical Affairs) from the University of Witwatersrand (South Africa).

Ezra R. Lowe, Ph.D.
Executive Director, Clinical and Preclinical Pharmacology

Ezra Lowe brings a depth of experience in clinical pharmacology, drug metabolism, and pharmacokinetics. He has a broad base of experience working with various drug formats across a diverse array of therapeutic areas. Prior to joining Galectin, Ezra was Senior Director, Clinical Pharmacology in Global R&D with the Bausch Health Companies.

Ezra holds a B.A. in Chemistry from Colgate University and a Ph.D. in Pharmacology from the University of Michigan. He is also an alumnus of the McKinsey Black Executive Leadership Program.

Marla Mills-Wilson
Executive Director, Clinical Operations

Marla Mills-Wilson has over 24 years of industry experience and brings to Galectin Therapeutics a deep experience in program management, project management, study operations, site management and progression across Phase 1 to 4 in a variety of therapeutic indications, including liver-related diseases, oncology, ophthalmology, and vaccines. She holds a B.S. from the University of Tennessee at Chattanooga, and continues to be a member of several professional clinical research organizations and is lean Six Sigma certified.

Jessica Kopaczewski
Associate Director, Clinical Operations

Jessica Kopaczewski is an accomplished clinical operations professional with over 24 years of diverse experience in the pharmaceutical research industry supporting global study operations, site management, and personnel management across Phase 1 to 4 studies in a variety of therapeutic indications including liver-related diseases, oncology, and infectious diseases.

Jessica holds a B.S. from the University of Wisconsin - Eau Claire in Biochemistry and Molecular Biology.

About Belapectin (GR-MD-02)

Belapectin (GR-MD-02) is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH 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. Belapectin binds to galectin-3 and disrupts its function. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis.

A Phase 2 study showed belapectin may prevent the development of esophageal varices in NASH cirrhosis, and these results provide the basis for the

conduct of the NAVIGATE trial. The NAVIGATE trial (NAVIGATEnash.com), entitled “A Seamless Adaptive Phase 2b/3, Double-Blind, Randomized, Placebo-controlled Multicenter, International Study Evaluating the Efficacy and Safety of Belapectin (GR-MD-02) for the Prevention of Esophageal Varices in NASH Cirrhosis” began enrolling patients in June 2020 and is posted on www.clinicaltrials.gov (NCT04365868).

Galectin-3 also has a significant role in cancer, and the Company is supporting a Phase 1 study in combined immunotherapy of belapectin and KEYTRUDA® in treatment of advanced melanoma and in head and neck cancer.

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 (formerly known as GR-MD-02) 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 non-alcoholic steatohepatitis (NASH) with cirrhosis, the most advanced form of NASH-related fibrosis. This is the most common liver disease and one of the largest drug development opportunities available today. Additional development programs are in treatment of combination immunotherapy for advanced melanoma and other malignancies. 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” 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 fatty liver disease 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 NAVIGATE clinical trial and any future clinical studies as modified to meet the requirements of the FDA 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. Global factors such as COVID-19 may limit access to NASH patient populations around the globe and slow trial enrollment and prolong the duration of the trial and significantly impact associated costs as well as impact other trial related activities including, amongst others, manufacturing and regulatory reviews. 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, 2020, 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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Galectin Therapeutics and its associated logo is a registered trademark of Galectin Therapeutics Inc. Belapectin is the USAN assigned name for Galectin Therapeutics’ galectin-3 inhibitor GR-MD-02.