



Galectin Therapeutics Discusses Corporate Transformation, Progress of NAVIGATE Trial and Outlines Strategy for Potential Phase 2 Cancer Immunotherapy Trial at Annual Meeting

December 13, 2021

NAVIGATE clinical trial in NASH cirrhosis now underway in all countries originally selected; full enrollment expected by mid-2022

Dr. Chetan Bettgowda, of Johns Hopkins, and Drs. Nishant Agrawal and Ari Rosenberg, both of the University of Chicago Medical Center, engaged to advise on path forward in oncology

Cancer immunotherapy efforts likely to focus on Head and Neck cancers

Shareholders approved all proposals, including the reelection of its Board of Directors

NORCROSS, Ga., Dec. 13, 2021 (GLOBE NEWSWIRE) -- Galectin Therapeutics, Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectins, provided an update on its strategy and clinical trial progress at its 2021 Annual Meeting, held virtually on December 3, and reported that shareholders approved all proposals, including the reelection of its Board of Directors.

"Compared to a year ago, Galectin Therapeutics has been transformed into a new company," said Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics. "The addition of highly-skilled and experienced professionals to our management team and advisors, most prominently Dr. Ben Carson, continued progress with our global NASH cirrhosis registration trial, and the Board's authorization to evaluate the initiation of a company-sponsored Phase 2 oncology program, enhances Galectin Therapeutics' position as the leader in galectin 3 inhibition."

During the Annual Meeting, Mr. Lewis and Dr. Pol Boudes, Chief Medical Officer of Galectin Therapeutics, made a presentation highlighting the following:

Update on Oncology Program

- Recently engaged three noted physicians – Dr. Chetan Bettgowda, from Johns Hopkins, and Dr. Nishant Agrawal and Dr. Ari Rosenberg, both from University of Chicago Medical Center – as consultants to help define the path forward in oncology.
- Strategic review with Drs. Bettgowda, Argawal and Rosenberg identified Head and Neck cancer patients as the population in highest need of new treatment, and a potential protocol for a Phase 2 trial of belapectin in combination therapy in this indication is under development.

Update on NAVIGATE Study in NASH Cirrhosis

- Despite the challenges presented by COVID-19, particularly outside the U.S., the NAVIGATE Phase 2b/3 trial in NASH cirrhosis has been initiated in all countries originally selected for participation.
- To balance the risks of the pandemic, additional countries are on the verge of being initiated and will soon contribute to global recruitment effort.

General Corporate Update

- In 2021, retained Dr. Ben Carson as a strategic consultant and hired four executives in key leadership positions. Expanded team possesses large pharma experience and operational expertise in virtually every aspect of drug development, including global registrations.

"Based on the feedback we receive from our investigators, there is no question in our mind that the NAVIGATE study is considered an important milestone by the medical community," concluded Pol Boudes, M.D., Chief Medical Officer of Galectin Therapeutics. "NAVIGATE should further trigger the interest of clinical researchers for cirrhosis in general, and NASH cirrhosis in particular, something that is also part of our mission at Galectin Therapeutics."

A replay of the Annual Meeting can be accessed here: <https://east.virtualshareholdermeeting.com/vsm/web?pvskey=GALT2021>

A transcript of the meeting is available here: <https://investor.galectintherapeutics.com/node/16661/html>

About Belapectin

Belapectin 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 (www.NAVIGATEdash.com), titled “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 has a significant role in cancer, and the Company has supported a Phase 1b study in combined immunotherapy of belapectin and KEYTRUDA in advanced melanoma and in head and neck cancer. This trial provided a strong rationale for moving forward into a Company-sponsored Phase 2 development program, which the company is exploring.

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. Advancement of these additional clinical programs is largely dependent on 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” 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 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 coronavirus may continue to impact NASH patient populations around the globe and slow trial enrollment and prolong the duration of the trial and significantly impact associated costs. 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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