Galectin Therapeutics Receives FDA Approval to Proceed with Combination Immunotherapy Trial in Head and Neck Cancer

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NORCROSS, Ga., Oct. 12, 2022 (GLOBE NEWSWIRE) -- Galectin Therapeutics, Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin-3, today announced that its Investigational New Drug (IND) application for belapectin in combination with a checkpoint inhibitor for the treatment of Head and Neck cancer has been filed with the U.S. Food and Drug Administration (FDA) Oncology division. Galectin Therapeutics also received a Study May Proceed letter for a Phase 2 clinical trial entitled “A Phase 2 Study of the Efficacy and Safety of Belapectin in Combination with Pembrolizumab (Keytruda®) as First-Line Treatment in subjects with Recurrent/Metastatic PD-L1 Positive Squamous Cell Carcinoma of the Head and Neck.”

Joel Lewis, President and Chief Executive Officer of Galectin Therapeutics, stated: “This second IND is a significant milestone and exemplifies the dedication of our team towards furthering development of belapectin to better the lives of patients in a variety of important diseases. Further, we acknowledge the input and review of this IND by our clinical experts, Drs. Chetan Bettegowda, Nishant Agrawal, and Ari Rosenberg. This effort resulted in the Company’s first fully electronic filing, which captured all available scientific data. This was a massive undertaking, and I am extremely proud of our team’s effort and dedication to completing this important milestone, while simultaneously managing our NASH cirrhosis trial.

As we celebrate this achievement, and explore options for our oncology program, the Company will continue its focus on our pivotal global NAVIGATE trial in NASH cirrhosis. We now have 11 additional active sites in Mexico and have made steady progress on enrollment, which, as we have previously stated, we expect to complete around the end of 2022.”

Pol Boudes, M.D., Chief Medical Officer of Galectin Therapeutics, stated that: “The prior investigator-initiated study in advanced metastatic melanoma and head and neck cancer using belapectin and Keytruda® provided a strong rationale for proceeding with this Phase 2 trial. To ensure the most appropriate design of our trial, we engaged in extensive consultations with expert oncologists in melanoma and head and neck cancer, which was crucial in ensuring we had the optimal clinical trial design. We are also thankful for the collaborative comments we received from the FDA during the submission process. There is a significant need to improve upon existing therapies in this area, and we hope this new combination will make a difference for patients affected with head and neck cancer.”

Mr. Lewis added: “The next steps for the Company’s oncology program will be to engage potential partners to collaborate on our program and planning for financing the trial, which, if successful, could begin next year. We will keep updating on our progress, as information becomes available.”

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.NAVIGATEnash.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 Head and Neck Cancer
Most head and neck cancers are derived from the mucosal epithelium in the oral cavity, pharynx, and larynx and are collectively known as head and neck squamous cell carcinoma (HNSCC). HNSCC was the sixth most common cancer worldwide in 2018. Most patients with HNSCC are diagnosed with locally advanced disease comprising stages III and IV. Among patients with locally advanced disease, 50-60% will develop locoregional relapse or distant metastases within 2 years. Despite advances in treatments, including surgery, radiotherapy, chemotherapy, and/or targeted systemic treatments, prognosis remains poor especially for patients with recurrent or metastatic HNSCC. In a Phase 1 study, the combination of belapectin with pembrolizumab enhanced the clinical and immunological effects of the PD-1 inhibitor and demonstrated an objective response rate of 33% in Subjects with HNSCC. Treatment with belapectin and pembrolizumab was also associated with fewer immune-mediated adverse events than anticipated with pembrolizumab monotherapy. The current study is designed to confirm these clinical results in a larger number of Subjects.

About Fatty Liver Disease with Advanced Fibrosis and Cirrhosis
Non-alcoholic steatohepatitis (NASH) has become a common disease of the liver with the rise in obesity and other metabolic diseases. NASH is estimated to affect up to 28 million people in the U.S. It is characterized by the presence of excess fat in the liver along with inflammation and hepatocyte damage (ballooning) in people who consume little or no alcohol. Over time, patients with NASH can develop excessive fibrosis, or scarring of the liver, and ultimately liver cirrhosis. It is estimated that as many as 1 to 2 million individuals in the U.S. will develop cirrhosis as a result of NASH, for which liver transplantation is the only curative treatment available. Approximately 9,000 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis or cirrhosis.

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 involved in multiple inflammatory, fibrotic, and malignant diseases, for which it has Fast Track designation by the U.S. Food and Drug Administration for NASH with advanced fibrosis and cirrhosis. 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, 2021, 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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