Galectin Therapeutics Announces Positive Top-Line Results from a Phase 1b Clinical Trial Extension of Belapectin in Combination with KEYTRUDA® in Advanced Metastatic Melanoma and Head and Neck Cancer

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- Belapectin and KEYTRUDA® combination immunotherapy in patients with treatment-refractory and progressive diseases shows a cancer control rate of 56% in melanoma and of 40% in head and neck cancer
- Melanoma patients in the study had a particularly severe prognosis, with four out of nine having choroidal primary tumors and six out of nine having liver metastasis
- No toxicities deemed related, probably related, or possibly related to Belapectin were reported
- Similar to the previously announced phase I study, the frequency and severity of toxicities observed with the combination were less than the anticipated toxicity with KEYTRUDA alone
- Portland's Earle A. Chiles Research Institute team, a division of Providence, led by principal investigator Dr. Brendan Curti, M.D., is further encouraged by the results that strengthen the rationale to conduct a larger, randomized controlled Phase 2 study

NORCROSS, Ga., July 09, 2021 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, and the Earle A. Chiles Research Institute, a division of the Providence Cancer Institute, today announced top-line clinical data from the extension cohort of an investigator-initiated Phase 1b clinical trial of Belapectin, a galectin-3 inhibitor, in combination with KEYTRUDA® (pembrolizumab) in patients with metastatic melanoma and head and neck cancer[1]. The study is conducted under the direction of Dr. Brendan D. Curti, M.D., a renowned cancer and melanoma expert[2].

The extension study enrolled nine melanoma patients and five head and neck squamous cell carcinoma cancer patients. Compared to the initial phase 1b patients, reported earlier, the cohort in this extension study was heavily pretreated with systemic therapy, including chemotherapy, immunotherapy with checkpoint inhibitors and cytokines, melanoma mutation-directed therapies (BRAF inhibitors and MEK inhibitors), as well as surgery and radiation therapies (external and radio-labeled). Patients also had a high burden of metastasis, with the lungs, soft tissues, and the liver being the most frequently involved organs. Four of the nine melanoma patients had a choroidal (ocular) tumor as a primary site of their cancer and had also developed liver metastasis.

The treatment consisted of Belapectin 4 mg/Kg of lean body mass administered every three weeks by infusion, after the infusion of pembrolizumab. Pembrolizumab was administered according to its label. Patients' response was evaluated at day 85, according to the Response Evaluation Criteria in Solid Tumors (RECIST) criteria. The median number of treatment cycles was four (range 3-15) for melanoma patients and five (range 4-8) for head and neck cancer patients.

Melanoma patient results included one partial response, four stable disease, and four progressive disease, providing a disease control rate of 56% (five out of nine patients). Head and neck cancer patients observed included two stable disease and three progressive disease, providing a disease control rate of 40% (two out of five patients).

The combination of Belapectin and pembrolizumab was well tolerated and appeared safe. The most frequent adverse event related to pembrolizumab, in six patients, was grade 1 (mild) pruritus (itching), a known and labeled side-effect of pembrolizumab. The second most frequent adverse event related to pembrolizumab was grade 2 fatigue in three patients. All other adverse events were mild (grade 1). There were no grade 3 or above adverse events. Similar to the initial phase 1 study results, the frequency and severity of toxicities related to pembrolizumab, notably immune-mediated adverse events, was less than anticipated. No adverse event was deemed related to belapectin.

Dr. Brendan Curti, M.D., the Principal Investigator of the study, stated, "Patients in this extension cohort had a significantly higher tumor burden when enrolled as compared to the initial study, and I view these results as encouraging. The results of the extension cohort support the rationale to conduct a Phase 2 randomized controlled-study to further evaluate the combination of belapectin with KEYTRUDA compared to KEYTRUDA alone and fully establish the benefit and immunological effects of this combination."

Dr. Ben Carson, M.D., Emeritus Professor of Oncology at the Johns Hopkins School of Medicine and Senior Advisor to Galectin Therapeutics, further commented, "A very significant volume of data has recently accumulated demonstrating the nefarious role that galectin-3 plays in the tumor micro-environment to stimulate tumor progression. More recently, we have been able to understand how the inhibition of galectin-3 helps to modify this microenvironment to possibly enhance the action of cancer immunotherapeutic endeavors while perhaps decreasing the side effects [1, 3]. With these new clinical data, I strongly support Galectin Therapeutics moving into the next step of development to bring hope to cancer patients in dire need of new treatments."

Dr. Pol Boudes, M.D., Chief Medical Officer at Galectin Therapeutics, added, "The advantageous tolerance and safety profile of the combination appears to be confirmed with the extension study. This may help patients to avoid frustrating side-effects that lead them to discontinue pembrolizumab (KEYTRUDA) for safety reasons even though they seem to benefit from the drug. A better tolerance would also lead to better compliance and, ultimately, a better risk/benefit profile of the combination. The apparent good safety profile is also consistent with what we see in cirrhotic patients who, like advanced cancer patients, are also very fragile. The dose used in the extension is indeed the highest dose that we are using in our NAVIGATE study in NASH cirrhosis."

“I look forward to launching a more ambitious oncology program for the combination of belapectin with a PD-1 inhibitor that could bring pivotal data to regulators,” concluded Dr. Boudes. “We are exploring the best options to operationalize such a program and believe that potential partners will interpret these confirmatory results as compelling.”

Additional information about the Providence clinical trial may be found at:
www.clinicaltrials.gov/ct2/show/NCT02575404

Additional information about the NASH NAVIGATE clinical study may be found at:
The NAVIGATE Study Clinical Trial in NASH Cirrhosis (navigatenash.com)

1. Curti BD, Koguchi Y, Leidner RS, *et al*. Enhancing Clinical and Immunological Effects of anti-PD-1 with Belapectin, a Galectin-3 Inhibitor. J ImmunoTher Cancer 2021;9:e002371.
2. Curti BD, Faries MB. Recent advances in the treatment of melanoma. N Engl J Med 2021;384:2229-40.
3. Sturgill ER, Rolig AS, Linch SN et al. Galectin-3 inhibition with belapectin combined with anti-OX40 therapy reprograms the tumor microenvironment to favor anti-tumor immunity, Oncoimmunol 2021 Mar 1;10(1):1892265

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.

About Providence Cancer Institute

Providence Cancer Institute, a part of Providence St. Joseph Health, offers the latest in cancer services, including diagnostic, treatment, prevention, education, support and internationally-renowned research. Providence Cancer Institute is home to the Earle A. Chiles Research Institute, a world-class research facility located within the Robert W. Franz Cancer Center in Portland, Oregon, and is a recognized leader in the field of cancer immunotherapy since 1993. Visit providenceoregon.org/cancer to learn more.

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 studies, 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 may be unable to raise funds or locate a partner for a possible controlled phase 2 study comparing Belapectin in combination with Keytruda® to Keytruda® alone; the Company’s current NAVIGATE clinical trial and any future clinical studies, including such possible controlled phase 2 study 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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