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Novel Cancer Treatment Combination Receives Approval to Begin First-in-Human Testing for Patients with Advanced Metastatic Melanoma

Trial to Evaluate the Safety and Efficacy of Immunomodulatory Compound, GM-CT-01, with Peptide Vaccine

NEWTON, Mass. & NEW YORK & BRUSSELS, Dec 08, 2011 (BUSINESS WIRE) -- Galectin Therapeutics, the Cancer Centre at the Cliniques universitaires Saint-Luc and the Ludwig Institute for Cancer Research (LICR) announced today that they will initiate a Phase 1/2 safety and efficacy trial testing a novel treatment combination in patients with advanced metastatic melanoma. The Belgian Federal Agency of Medicine and Health Products (FAMHP) granted approval to evaluate Galectin Therapeutics' carbohydrate-based galectin receptor inhibitor, GM-CT-01, together with an LICR peptide vaccine. The trial will enroll up to 46 patients from four clinical centers in Belgium and Luxembourg.

"This trial marks Galectin Therapeutics entry into the clinic with one of our lead programs and represents a substantial opportunity for us to learn about the broad immunotherapy potential for inhibiting galectin proteins which are over expressed by nearly all tumors," commented Peter G. Traber, M.D., President, Chief Executive Officer and Chief Medical Officer, Galectin Therapeutics.

"Preclinical studies have shown that GM-CT-01 enhances the ability of tumor-infiltrating T-lymphocytes to kill cells. Therefore, it is our hope that combining GM-CT-01 with an anti-cancer vaccine will induce a more efficient immune response that will aid in the shrinkage of metastatic tumors in patients with advanced metastatic melanoma," said Dr. Pierre van der Bruggen of LICR.

All patients will receive either MAGE-3.A1 or NA17.A2 injections at three-week intervals throughout the study and GM-CT-01 intravenously every three days, beginning after the third dose of the peptide vaccine. Patients with at least one superficial metastatic lesion will also receive GM-CT-01 at the site of the lesion.

Partial or complete response will serve as the efficacy endpoint for the trial. Patient enrollment will commence in early 2012, and initial safety data are expected by the end of 2012.The Cliniques universitaires Saint-Luc and LICR will fund the first stage of the trial, and the second stage will be funded through grants and/or Galectin Therapeutics funds.

Each of the two peptide vaccines has already been tested in advanced melanoma patients, either alone, with or without immunological adjuvant, or in other vaccine combinations. These vaccines were well tolerated and were associated with evidence of tumor regression in a minority of patients (5 to 20%). The GM-CT-01 compound has shown initial success in preclinical studies in improving the efficacy of T-lymphocytes in killing cells. GM-CT-01 has proven safe in 100 patients in previous human studies.

There are more than 100,000 individuals around the world diagnosed with melanoma each year. Current treatment options for patients with melanoma include chemotherapy, radiotherapy and immune modulating drugs, all of which have shown limited success in shrinking tumors and extending survival time in a subset of patients with advanced disease. This Phase 1/2 study will test a novel treatment concept: combining active vaccination and immunomodulatory agents to evaluate whether they are safe and have an impact in shrinking or eliminating metastatic melanoma tumors.

"We look forward to enrolling patients in this first-of-its-kind study to examine the impact of inhibiting tumor-secreted galectins for enhancing the ability of the immune system to attack cancer cells and have a therapeutic effect in patients with melanoma," said Prof. Jean-François Baurain of the Cancer Centre at the Cliniques universitaires Saint-Luc, the principal investigator on the trial.

About Galectin Therapeutics

Galectin Therapeutics (OTC: GALT) is developing promising carbohydrate-based therapies for fibrotic liver disease and cancer based on the Company's unique understanding of galectin proteins, key mediators of biologic function. We are leveraging extensive scientific and development expertise as well as established relationships with external sources to achieve cost effective and efficient development. We are pursuing a clear development pathway to clinical enhancement and commercialization for our lead compounds in liver fibrosis and cancer. Additional information is available at http://www.galectintherapeutics.com.

About the Ludwig Institute for Cancer Research Ltd

The Ludwig Institute for Cancer Research Ltd (LICR) is a global, non-profit institute that integrates laboratory and clinical

research, and translates its discoveries into applications for human benefit. LICR is a world-wide network of research sites located across Asia, Australasia, Europe, and North and South America. The predominant goal of this international institute has remained focused on the understanding and control of cancer since its establishment in 1971. Its innovative structure, however, has enabled LICR to have the flexibility necessary to adapt, keep pace and take advantage of advancements made in cancer research over the past several decades. http://www.licr.org

About the Cancer Centre at Cliniques universitaires Saint-Luc

The Cancer Centre of Cliniques universitaires Saint-Luc, Brussels Belgium, is a leading reference center in Europe. Its location within an academic hospital guarantees high-level quality and comprehensive care to all patients. Fifteen multidisciplinary clinical programs, focused on specific organ or disease types, offer tailor-made care for each patient and cutting-edge research to fight cancer. Most Cancer Centre physicians have close collaborations with worldwide recognized cancer research institutes such as the Ludwig Institute for Cancer Research Ltd (LICR) and the European Organization for Research and Treatment of Cancer (EORTC), collaborating on various research programs targeting a better knowledge of cancer mechanisms and treatment. http://www.centreducancer.be

Forward Looking Statements

This press release contains, in addition to historical information, 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 our current expectations and are subject to factors and uncertainties which could cause actual results to differ materially from those described in the statements. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others: incurrence of operating losses since our inception, uncertainty as to adequate financing of our operations, extensive and costly regulatory oversight that could restrict or prevent product commercialization, inability to achieve commercial product acceptance, inability to protect our intellectual property, dependence on strategic partnerships, product competition, and others stated in risk factors contained in our SEC filings. We cannot assure that we have identified all risks or that others may emerge which we do not anticipate. You should not place undue reliance on forward-looking statements. Although subsequent events may cause our views to change, we disclaim any obligation to update forward-looking statements.

SOURCE: Galectin Therapeutics Inc.

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