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# Galectin Therapeutics Announces Initiation of Phase 1/2 Trial of Novel Combination Therapy for Advanced Metastatic Melanoma

NEWTON, Mass.--(BUSINESS WIRE)--May. 15, 2012-- Galectin Therapeutics (NASDAQ: GALT) (“the Company”), the leader in developing carbohydrate-based therapeutic compounds to inhibit galectin proteins for the therapy of liver fibrosis and cancer, today announced that the first patient has been dosed in a Phase 1/2 trial evaluating the safety and efficacy of a novel treatment combination for the treatment of advanced metastatic melanoma. The trial, being conducted in collaboration with the Cancer Centre at the Cliniques universitaires Saint-Luc and the Ludwig Institute for Cancer Research (LICR), is evaluating Galectin Therapeutics’ carbohydrate-based galectin inhibitor compound, GM-CT-01, in combination with a Ludwig Institute peptide vaccine.

“This first-in-human Phase 1/2 study combines active vaccination and immunomodulatory agents to enhance the immune system’s ability to kill cancerous cells,” said Prof. Jean-François Baurain of the Cancer Center at the Cliniques universitaires Saint-Luc, the principal investigator of the trial. “The initiation of this trial is an important step in evaluating a potential new treatment modality for patients with advanced metastatic melanoma, who experience limited success with currently available therapies.”

“Galectin Therapeutics is committed to realizing the promise of galectin inhibition in cancer immunotherapy, and this trial of vaccine plus galectin inhibitor in metastatic melanoma is a critical first step in that effort,” commented Peter Traber, M.D., CEO of Galectin Therapeutics. “We are honored to work with Dr. Baurain and the team at the Ludwig Institute and look forward to progress in this study.”

In the Phase 1/2 study, patients will receive a peptide vaccine (either MAGE-3.A1 or NA17.A2) injection 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. The primary endpoint is partial or complete response.

The Cliniques universitaires Saint-Luc and LICR are funding the first stage of the trial, and the second stage will be funded through grants and/or Galectin Therapeutics funds.

**About the Phase 1/2 Trial**

Patients enrolled in the trial will have metastatic melanoma with regional or distant metastatic disease with either HLA-A1 type and MAGE-3 or HLA-A2 type and NA17.A2 expressed by the tumor. Patients will be divided in two treatment arms that will be run in parallel. Patients with at least one measurable lesion will be assigned to group 1 and will receive peptide vaccinations and systemic GM-CT-01 injections. Patients with at least one measurable and at least one superficial metastasis will be assigned in priority to group 2 and will receive peptide vaccinations, systemic GM-CT-01 administrations and peri-tumoral administration of GM-CT-01. The vaccine matching the patient’s HLA type and the gene expression of the patient’s tumor (if both antigens are expressed the patient will receive both peptides) will be administered subcutaneously every three weeks on six occasions. GM-CT-01 will be administered every three days after each of the third through sixth vaccination and, in those patients with superficial metastases, additionally by peri-tumoral injection on the same schedule. In Stage 1, six patients will be enrolled in each arm. If no CR or PR is observed, the trial will be stopped, otherwise, an additional 17 patients will be enrolled in Stage 2. Tumor staging will be performed before inclusion and after treatment. Immunological analysis will be performed on T-lymphocytes prior to treatment and after two and six vaccinations. Primary endpoints include safety and tumor response according to Response Evaluation Criteria in Solid Tumors (RECIST 1.1) guidelines. Secondary endpoints will include overall survival and immunological measurements. Results of Stage 1 are expected within one year.

**About Galectin Therapeutics**

Galectin Therapeutics (NASDAQ: 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.

**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

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