



Jennerex and Transgene Present Positive Clinical Data from Phase 2 Trial of JX594/TG6006 in Sorafenib-Refractory Liver Cancer Patients

Key Clinical Endpoints Met:

JX594/TG6006 can be safely and efficiently delivered through systemic route and standard-of-care Sorafenib can be safely administered sequentially after JX594/TG6006, opening door to new clinical perspectives

Berlin, Germany, September 17, 2012 - Jennerex, Inc., a private, clinical-stage biotherapeutics company focused on the development and commercialization of first-in-class targeted oncolytic immunotherapies and Transgene SA (Euronext Paris: FR0005175080), presented interim Phase 2 clinical data of JX594/TG6006 delivered first intravenously and subsequently through intra-tumoral route demonstrating safety as well as disease control and tumor responses in patients with hepatocellular carcinoma (liver cancer, HCC). The data were presented in an oral presentation at the International Liver Cancer Association (ILCA¹) Annual Meeting in Berlin, Germany, by Mong Cho, M.D., from Pusan National University Yangsan Hospital, South Korea².

25 Asian patients with advanced HCC, 20 of whom were refractory to sorafenib and 5 of whom were treatment-naïve, were treated with an initial intravenous dose of JX594/TG6006. The majority of patients, 23, then received sequential intra-tumoral doses of JX594/TG6006 at weeks one and three, followed by sorafenib.

The primary objective of this study was to determine the safety of JX594/TG6006 followed by sorafenib in patients with advanced HCC. The sequential treatment regimen was well tolerated with transient flu-like symptoms and transient leukopenia being the most common side effects related to JX594/TG6006. The sorafenib side effects observed were consistent with the expected toxicity profile of this product.

Secondary endpoints included the effect of the sequential treatment of JX594/TG6006 followed by sorafenib on disease control and tumor response. Evidence of antitumor activity was observed in both sorafenib-naïve and sorafenib-refractory patients (see [“About this Trial”](#)).

Importantly, this trial also demonstrated the feasibility of the systemic administration of the product (through intravenous injection).

¹ ILCA, Berlin, Germany, from 14-16 September 2012.

² See abstract (#2012-1304) entitled “Phase 2 Trial of JX-594, A Targeted Multi-Mechanistic Oncolytic Vaccinia Virus, Followed By Sorafenib In Patients With Advanced Hepatocellular Carcinoma (HCC).

“Our ability to deliver JX594/TG6006 intravenously to liver cancer tumors, further confirmed by these encouraging data, is a key attribute that sets it apart from other therapies in the class of oncolytic immunotherapies,” stated David H. Kirn, M.D., founder, Chief Medical Officer and President of R&D of Jennerex. “In the Phase 2 trial presented at ILCA, JX594/TG6006 demonstrated its ability to selectively target and destroy tumors following intravenous infusion. This finding confirms the ability of JX594/TG6006 to target both primary and metastatic, or distant, tumors which we believe is important in this HCC patient population and most cancers.”

“We have treated more than 160 patients with JX594/TG6006 to date and are actively enrolling a multinational Phase 2b study in second line treatment of liver cancer patients, a Phase 2b in first line HCC patients and a Phase 2 study in colorectal cancer. The data presented today build on the growing body of promising clinical data showing that JX594/TG6006 has a direct anti-tumor effect and can stimulate an immune response killing cancer cells,” stated Laurent Fischer, M.D., President and Chief Executive Officer of Jennerex. *“We are excited with the progress we are making in our JX594/TG6006 program and believe it has the potential to advance patient care across multiple types of cancer.”*

Philippe Archinard, Chairman & CEO of Transgene, stated : *“These data are very important as, besides confirming the interesting safety and efficacy profile of the product, they clearly show that the virus can effectively and safely be delivered to the tumor site through a systemic route. These data together with the upcoming results expected from the three on-going clinical studies should pave the way for our planned Phase 3 trial in liver cancer.”*

About this Trial:

25 Asian patients with advanced HCC, 20 of whom were refractory to sorafenib and 5 of whom were treatment-naïve, were treated with an initial intravenous dose of JX594/TG6006. The 23 patients then received sequential intratumoral doses of JX594/TG6006 at weeks one and three, by sorafenib.

Following treatment with JX594/TG6006 alone at four weeks, 62 percent of patients had disease control as measured by modified RECIST (tumor burden measurement). Tumor biopsies of four patients following intravenous infusion showed four of four patients had local infection of JX594/TG6006 in tumor tissue while normal liver tissue was not affected, providing further evidence of JX-594/TG6006’s tumor selectivity and the ability to administer JX594/TG6006 intravenously. Furthermore, after 6 or 12 weeks, 59 percent of patients had disease control as measured by modified RECIST and 75 percent of patients had objective responses by Choi criteria. 85 percent of patients had disease control by mRECIST and /or Choi response.

JX594/TG6006: A Multi-Mechanistic Approach To Targeting Cancer

JX594/TG6006 is a proprietary, engineered oncolytic immunotherapy designed to selectively target and destroy cancer cells through three diverse mechanisms of action: 1) the lysis of cancer cells 2) the stimulation of an immune response against cancer cells, (i.e., active immunotherapy), and 3) the shutdown of the blood supply to tumors. Phase 1 and Phase 2 clinical trials in multiple cancer types to date have shown that JX594/TG6006, delivered either directly into tumors or intravenously, induces tumor shrinkage and/or necrosis and is well-tolerated (over 160 patients treated to date). Objective tumor responses have been demonstrated in a variety of cancers including liver, colon, kidney, lung cancer and melanoma. JX594/TG6006 has had a favorable, predictable and generally mild safety profile to date which includes flu-like symptoms that resolve in 24 to 48 hours.

JX594/TG6006 takes advantage of the natural attributes of poxviruses and was engineered to target and destroy solid tumors both systemically and locally. The vaccinia virus backbone of JX594/TG6006 has been used safely in millions of people as part of a worldwide vaccination program. This strain naturally targets cancer cells due to common genetic abnormalities in cancer cells. JX594/TG6006 was engineered to enhance this cancer-selectivity by inactivating its thymidine kinase (TK) gene and encode the immunogenic GM-CSF gene, to enhance the immune response against cancer cells.

Hepatocellular Carcinoma: A Global Unmet Need

Hepatocellular carcinoma is the fifth most common cancer worldwide and the third leading cause of cancer death, with over 600,000 new cases diagnosed annually resulting in more than 90 percent mortality. The annual incidence rate in the U.S., Europe, Japan and China are estimated to be 20,000, 55,000, 40,000 and 350,000 patients, respectively. The only treatment approved for HCC is sorafenib. There is no treatment approved for patients who fail sorafenib.

About Jennerex :

Jennerex, Inc. is a clinical-stage biotherapeutics company focused on the development and commercialization of first-in-class, breakthrough targeted oncolytic immunotherapy products for cancer. The Company's lead product JX-594 is currently in an international, randomized Phase 2b clinical trial (TRAVERSE) in patients with advanced primary liver cancer who have failed sorafenib therapy. In addition, JX-594 is being tested in the same patient population in combination with sorafenib. JX-594 is also in a Phase 1 clinical trial in patients with treatment-refractory colorectal cancer. Published studies designed to establish optimal dose levels and the safety profile of JX-594 have shown its ability to selectively target and cause destruction of a variety of common solid tumor types and trigger a potent immune response. JX-594 and other product candidates under development are designed to attack cancer tumors through three diverse mechanisms of action: the lysis of cancer cells through targeted viral replication, the ablation of the blood supply to tumors through vascular targeting and destruction and the stimulation of the body's immune response against the cancer. Jennerex is headquartered in San Francisco and has related research and development operations in Ottawa, Canada and Busan, South Korea. For more information about Jennerex, please visit www.jennerex.com.

About Transgene SA:

Transgene, a member of the Institut Mérieux Group, is a publicly traded French biopharmaceutical company dedicated to the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases and has four compounds in Phase 2 clinical development: TG4010 and JX594/TG6006 having already completed initial Phase 2 trials, TG4001 and TG4040. Transgene has concluded strategic agreements for the development of two of its immunotherapy products: an option agreement with Novartis for the development of TG4010 to treat various cancers and an in-licensing agreement with US-based Jennerex, Inc. to develop and market JX594/TG6006, an oncolytic virus. Transgene has bio-manufacturing capacities for viral-based products. Additional information about Transgene is available at www.transgene.fr.

Disclaimer:

This press release contains certain forward-looking statements. Although the company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. In particular, the Company's ability to commercialize its first product depends on the continuing success of clinical studies, ongoing financing for further product developments and marketing launch, a positive response from the medical community regarding the product's costs and effectiveness. For a discussion of risks and uncertainties which could cause the company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Document de Reference prospectus, which is available on the AMF website (<http://www.amf-france.org>) or on Transgene's website (www.transgene.fr). This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in Transgene in any country.

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