Transgene and Jennerex Announce Final Data at AASLD From JX594/TG6006 Randomized Phase 2 Clinical Trial Showing Statistically Significant Survival Benefit in Patients with Advanced Liver Cancer

Median survival of 13.8 months (high dose) vs. 6.7 months (low dose)

Strasbourg, France and San Francisco, California, November 7, 2011—Transgene (Euronext Paris: FR0005175080) and Jennerex, Inc. announce final data from a randomized dose-ranging Phase 2 clinical trial of JX594/TG6006 in patients with advanced liver cancer showing a statistically significant benefit in overall survival for the high JX594/TG6006 dose group versus the low dose group. The final data from the HEP007 trial demonstrated that the risk of death for patients who received JX594/TG6006 at the high dose was markedly reduced (by nearly 60 percent; hazard ratio = 0.41) when compared to patients randomized to a low dose control (one-tenth of the high dose). The median overall survival for high and low dose groups was 13.8 months versus 6.7 months, respectively (p = 0.029 for superiority of the high dose). The percent of patients alive at one year was 66 percent versus 23 percent in high- and low-dose groups, respectively (Kaplan-Meier estimate). JX594/TG6006 was well-tolerated with patients experiencing transient flu-like symptoms that generally resolved within 24 hours. Clinical investigators enrolled 30 patients at sites in the United States, Canada and South Korea.

The data were presented by Tony Reid, M.D., Ph.D., professor of medicine, hematology/oncology, director of clinical investigation, and the tumor growth, invasion and metastasis program, Moores UCSD Cancer Center at the University of California, San Diego. Dr. Reid presented during the late-breaking oral session at the 62nd Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco, California. The abstract (#LB-1) was entitled "A Randomized, Controlled Phase 2 Clinical Trial of JX594, a Targeted Multi-Mechanistic Oncolytic Poxvirus, in Patients with Advanced Hepatocellular Carcinoma: Final Data."

A randomized, placebo-controlled Phase 2b clinical trial of JX594/TG6006 in patients with hepatocellular carcinoma (HCC) having failed sorafenib (Nexavar®) treatment was recently initiated. This trial (TRAVERSE), conducted globally with Jennerex’s partners, is evaluating survival in advanced HCC patients who have either progressed or exhibited intolerance after treatment with sorafenib, the current standard of care.

"These data showing an improvement in overall survival are very encouraging—particularly when coupled with the favorable tolerability profile of JX594/TG6006 experienced in this and prior clinical trials. Another therapeutic option to treat patients with HCC, the third leading cause of cancer death globally, is urgently needed" stated Dr. Reid, a clinical investigator on the HEP007 clinical trial.

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“The strength of these data—showing a statistically significant benefit in overall survival—gives us great confidence in the potential of JX594/TG6006 to benefit patients with liver and other types of cancer world-wide” stated David H. Kirn, M.D., President and Chief Medical Officer of Jennerex. He added: “Based on these clinical data, and clinical data we have previously published, we are accelerating the development of JX594/TG6006. Together with our partners, we are initiating a more expansive late-stage TRAVERSE clinical trial of JX594/TG6006 in HCC, and we are moving into Phase 1/2 trials in additional cancer types, including ras mutant and Erbitux-refractory colorectal cancer.”

“The clinical data presented by Jennerex at AASLD once again validates our commitment to JX594/TG6006 and demonstrates that the product could really change the treatment paradigm in liver cancer. Should these findings be confirmed in late stage clinical trials, and notably in the TRAVERSE study, then the chances of JX594/TG6006 coming to the market will be very high” stated Philippe Archinard, Chairman and CEO of Transgene.

Other Recent Clinical Data for JX594/TG6006 in Liver Cancer:

In a second Phase II trial which sequentially combined intravenous and intratumoral administration of JX594/TG6006 and sorafenib treatment, interim data from 15 patients, including a subgroup of 10 who have failed previous treatment with sorafenib, demonstrated tumor responses by Choi criteria (a measure of tumor necrosis) in both injected and non-injected tumors in 8 of 11 evaluable patients. Tumor responses were maintained for up to 15 months post JX594/TG6006 treatment initiation. Significant tumor necrosis following JX594/TG6006 and sorafenib was observed in 6 of 7 evaluable sorafenib resistant patients (86 percent).

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. Currently, there is only one approved agent for HCC, a drug called sorafenib (Nexavar®), which is associated with moderate efficacy (tumor response rate of ~2%) and a side effect profile that results in treatment discontinuation in one fourth to one third of patients.

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

JX594/TG6006 is a proprietary, engineered oncolytic virus that is designed to selectively target and destroy cancer cells. JX594/TG6006 is designed to attack cancer through three diverse mechanisms of action: 1) the lysis of cancer cells through viral replication, 2) the shutdown of the blood supply to tumors through vascular targeting and destruction, and 3) the stimulation of the body's immune response against cancer cells, i.e., active immunotherapy. Phase I and Phase II clinical trials in multiple cancer types to date have shown that JX594/TG6006, delivered either directly into tumors or systemically, induces tumor shrinkage and/or necrosis and is well-tolerated by patients (over 120 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 a favorable safety profile with predictable and generally mild side effects that typically include flu-like symptoms that resolve in 24 to 48 hours.
About Transgene:

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 II clinical development: TG4010 and JX594/TG6006 having already completed initial Phase II 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.

About Jennerex:

Jennerex, Inc. is a clinical-stage biotherapeutics company focused on the development and commercialization of first-in-class, breakthrough targeted oncolytic products for cancer. The Company's lead product JX594/TG6006 is currently in an international, randomized Phase IIb clinical trial (TRAVERSE) in patients with advanced primary liver cancer who have failed sorafenib therapy. In addition, JX594/TG6006 is being tested in the same patient population in combination with sorafenib. JX594/TG6006 is also in a Phase I clinical trial in patients with treatment-refractory colorectal cancer. Published studies designed to establish optimal dose levels and the safety profile of JX594/TG6006 have shown its ability to selectively target and cause destruction of a variety of common cancer types. JX594/TG6006 and other product candidates under development are designed to attack cancer tumors through three diverse mechanisms of action: the lysis of cancer cells through 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 Pusan, South Korea. For more information about Jennerex, please visit www.jennerex.com.

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.com). 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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