



# Jennerex and Transgene Announce the Presentation of Positive Clinical Data of JX-594 in Patients with Liver Tumors

**San Francisco, California and Illkirch, France, April 5, 2011--**Jennerex, Inc., a private clinical-stage biotherapeutics company focused on the development and commercialization of first-in-class targeted oncolytic products for cancer, and Transgene (NYSE Euronext Paris: FR0005175080), a bio-pharmaceutical company specialized in the development of immunotherapeutic products, today announced that new data from Phase 1 and 2 clinical studies of JX-594 were presented in an oral presentation at the 46<sup>th</sup> Annual Meeting of the European Association for the Study of the Liver (EASL) over the weekend at the Internationales Congress Centrum in Berlin, Germany.

The data from abstract #LB-283, entitled "JX-594, A Targeted Multi-Mechanistic Oncolytic Poxvirus, is Well-Tolerated and Exhibits Anti-Tumor Activity in Patients with Primary Liver Cancer and Liver Metastases," were presented by Caroline Breitbach, Ph.D., director of translational research.

"We are pleased to present these data on JX-594 at the EASL meeting, as they provide further evidence that both primary liver cancer and metastases to the liver can be treated safely with JX-594, with transient flu-like symptoms being the most common adverse events. Anti-cancer activity continues to be clearly demonstrated in a broad spectrum of common solid tumor types," said David H. Kirn, M.D., president and chief executive officer of Jennerex.

"We look forward to reporting additional clinical results in patients with advanced liver cancer from two ongoing studies—a randomized Phase 2 trial of JX-594 evaluating survival across two dose groups, and a Phase 2 clinical trial evaluating JX-594 in combination with sorafenib," added Philippe Archinard, chairman and chief executive officer of Transgene.

# **Clinical Results**

This presentation highlighted data from 35 patients with either primary liver cancer, known as hepatocellular carcinoma (HCC), or cancer metastases to the liver (including colorectal cancer, melanoma and renal cancer). All patients were given intratumoral (IT) injections (up to eight treatments) over the course of JX-594 therapy. Twenty-three patients (66%) exhibited significant tumor necrosis and responses by modified Choi criteria (decreased tumor density). Choi responses have also been documented in non-injected tumors, consistent with prior data on JX-594. Seven patients (20% of evaluable) also exhibited objective response by Response Evaluation Criteria in Solid Tumor (RECIST) criteria, including two complete responses upon long-term follow-up. Twenty patients (57%) had stable disease as defined by RECIST criteria.

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#### About JX-594

JX-594 is a proprietary, engineered oncolytic virus that is designed to selectively target and destroy cancer cells. JX-594 is designed to attack cancer 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 cancer cells (ie active immunotherapy). Phase 1 and Phase 2 clinical trials in multiple cancer types to date have shown that JX-594, delivered either directly into tumors or systemically, induces tumor shrinkage and/or necrosis and is well-tolerated by patients. Objective tumor response has been demonstrated in a variety of cancers including liver, colon, kidney, lung and melanoma.

Transgene holds an exclusive license to develop and commercialize JX-594 in Europe and neighboring countries. Green Cross Corporation, a leading company in the development, manufacturing, and commercialization of viral vaccines and other biological products, holds an exclusive license to develop and commercialize JX-594 in South Korea, and Lee's Pharmaceutical Ltd. holds an exclusive license to develop and commercialize JX-594 in China.

# About Liver Cancer and Hepatocellular Carcinoma (HCC)

Hepatocellular carcinoma (HCC) is the fifth most common cancer and the third most common cause of cancer-related deaths world-wide with about 660,000 patients dying from the disease annually. Most HCC cases develop on the background of chronic liver cirrhosis; in regions with the highest incidence of HCC, East Asian and African countries, the majority of cases are related to hepatitis B; in developed Western countries and Japan the disease is commonly related to hepatitis C, heavy alcohol consumption and non-alcoholic fatty liver due to metabolic syndromes such as diabetes and obesity. There is accumulating evidence that the incidence of HCC is increasing in Western countries. Despite recent advances, the treatment of advanced HCC remains a significant unmet medical need with a median expected survival under current therapies of less than one year.

## 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 JX-594 is currently in two Phase 2 clinical trials in patients with primary liver cancer—an international, randomized, Phase 2 clinical trial, and a Phase 2 study of JX-594 in combination with sorafenib. 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 cancer types. 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 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 <u>www.jennerex.com</u>.

# 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 five compounds in clinical development: TG4010 and JX594 (TG6006) having completed initial phase II trials, TG4001 in phase IIb trial, TG4040 in phase II trial and TG4023 in phase I trial. 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 Biotherapeutics, Inc., to develop and market JX594 (TG6006), an oncolytic product.

Transgene has bio-manufacturing capacities for viral-based products. Additional information about Transgene is available on the internet at <u>www.transgene.fr</u>

# Cautionary note for Transgene regarding forward-looking statements

This press release contains forward-looking statements referring to the joint clinical testing and development and commercial potential of JX-594. Clinical testing and successful product development and commercialization depend on a variety of factors, including the timing and success of future patient enrolment, the risk of unanticipated adverse patient reactions, regulatory approval and the level of demand for the product by the medical community. Results from future studies with more data may show less favorable outcomes than prior studies, and there is no certainty that product candidates will ever demonstrate adequate therapeutic efficacy or achieve regulatory approval or commercial success. In addition, forward-looking statements regarding product development, testing and marketing costs are by the nature subject to uncertainties as a result of unforeseen difficulties and expenses which may arise, and future product development costs may exceed current expectations. For further information on the risks and uncertainties involved in the testing and development of Transgene's product candidates, see Transgene's Document de Référence on file with the French Autorité des marchés financiers on its website at http://www.amf-france.org and Transgene's website at www.transgene.fr.

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