



# Jennerex and Transgene Announce Initiation of Clinical Trial of Intravenous JX-594 in Patients with Refractory Metastatic Colorectal Cancer

**San Francisco, California and Illkirch, France, December 16, 2010-**-Jennerex, Inc., a private clinical-stage biotherapeutics company focused on the development and commercialization of first-inclass 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 enrollment and treatment of patients in a Phase 1b clinical trial has been initiated to evaluate JX-594 in patients with advanced metastatic, refractory colorectal cancer (CRC). The study will be performed in Korea, where Green Cross Corporation holds market rights for JX-594.

"The initiation of this study marks an important step forward in the development of JX-594 for a second major oncology indication. With a significant and growing population of colorectal cancer patients who have failed existing therapies or for whom existing therapies are not appropriate, we believe JX-594, with its unique mechanisms of action and demonstrated tumor response in preclinical models of CRC, may provide an important new therapeutic modality for patients around the world suffering from this devastating cancer," said David H. Kirn, M.D., president and chief executive officer of Jennerex.

"The study design for this trial builds on our joint experience and positive clinical results using JX-594 to treat liver cancer and represents an important milestone which is our ability to administer multiple doses intravenously," added Philippe Archinard, chairman and chief executive officer of Transgene.

The intravenous, open-label, multi-dose-escalation study is being conducted at Samsung Cancer Center in Seoul, South Korea. The study will enroll up to 15 patients with metastatic colorectal cancer that have failed both oxaliplatin-based and irinotecan-based chemotherapy regimens, and whose tumors harbor ras mutations and/ or are refractory to Erbitux therapy. Patients enrolled in the trial will receive biweekly intravenous infusions of JX-594 at one of three dose levels to evaluate the safety, tolerability and maximum tolerated dose of JX-594 for the treatment of CRC.

# 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 reduction of the blood supply to tumors through vascular targeting and destruction, and the stimulation of the body's immune response against cancer cells. 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 Colorectal Cancer**

Colorectal cancer is the second leading cause of cancer-related deaths in the United States and according to the World Health Organization, it accounts for approximately 639,000 deaths worldwide each year. Approximately one in 20 people in the United States will develop CRC during their lifetime, with the risk increasing with age. Ninety percent of all CRC cases are diagnosed in people over the age of 50. The exact cause of colorectal cancer is not known, although there are certain known risk factors that increase the chance of developing colorectal cancer. These risk factors include inflammatory bowel disease, family history of CRC, certain genetic syndromes, smoking, low fruit and vegetable intake and a sedentary lifestyle.

## **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. In addition to the Phase 1b clinical trial in CRC, the Company's lead product JX-594 is currently in two mid-stage clinical trials in patients with primary liver cancer—an international, randomized, Phase 2 dose-response clinical trial, and a Phase 2 study 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 a variety of common cancer tumor 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 reduction of the blood supply to tumors through vascular targeting and destruction and the stimulation of the body's immune response against cancer cells. 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.

## 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 clinical development: TG4010 having completed Phase 2 trials, TG4001/RG3484 in Phase 2b trial, TG4040 in Phase 2 trial and TG4023 in Phase 1 trial. Transgene has concluded strategic agreements for the development of two of its immunotherapy products:

- a license agreement with Roche for the development of TG4001/RG3484 to treat HPVmediated diseases, and
- an option agreement with Novartis for the development of TG4010 to treat various cancers.

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 Trangene'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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