



## **Jennerex Reports Positive Mechanistic Proof-of-Concept Clinical Trial Results Using JX-594 to Treat Metastatic Melanoma**

**– Data Published in Current Issue of *Molecular Therapy* –**

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**San Francisco, USA, and Illkirch, France, August 2<sup>nd</sup>, 2011** – Jennerex, Inc., a private clinical-stage biotherapeutics company focused on the design, 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, announced today that data providing a mechanistic proof-of-concept for JX-594 injected intra-tumorally to patients with metastatic melanoma were published in the peer-reviewed journal *Molecular Therapy*.

*“This clinical trial in metastatic melanoma provides additional key information for our JX-594 program and complements the on-going clinical development of JX-594, which is expected to enter a randomized Phase 2b trial in advanced liver cancer later this year,”* said David Kirn, M.D., President and Chief Executive Officer of Jennerex. *“Specifically, JX-594 replication was observed following multiple rounds of intratumoral JX-594 therapy, providing proof-of-concept data for the potential benefit of chronic administration regimens of the product.”*

*“These results, which complement data recently obtained and published, notably in advanced liver cancer, further strengthen the potential of the oncolytic virus as a new therapeutic alternative”* said Philippe Archinard, Chairman and CEO of Transgene.

The mechanistic proof-of-concept study enrolled 10 treatment-refractory Stage IV melanoma patients, eight of whom completed the study. Patients received up to nine weekly intratumoral injections of JX-594 at a low dose (less than 10 percent of the dose given in other JX-594 trials). Evidence of JX-594 activity was assessed in blood samples and tumor biopsies. Blood samples collected over the course of treatment demonstrated JX-594 replication after repeated dosing as well as the expression and functionality of JX-594 encoded transgenes. Tumor biopsies showed tumor cell necrosis (death) and immune cell recruitment into tumors. JX-594 was safe and well-tolerated, with flu-like symptoms as the most common side effect for patients.

### **JX-594: A Multi-Mechanistic Approach To Targeting Cancer**

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: 1) the lysis of cancer cells through viral replication, 2) the reduction 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 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 (over 100 treated to date). Objective tumor responses have been demonstrated in a variety of cancers including liver, colon, kidney, lung and melanoma. JX-594 has a favorable safety profile with predictable and generally mild side effects that typically include flu-like symptoms that resolve in 48 to 72 hours.

The poxvirus strain backbone of JX-594 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 defects in cancer cells. JX-594 was engineered to enhance this natural safety and cancer-selectivity by deleting its thymidine kinase (TK) gene, thus making it dependent on the cellular TK expressed at persistently high levels in cancer cells. To enhance product efficacy, JX-594 is also engineered to express the GM-CSF protein. GM-CSF complements the cancer cell lysis work of the product candidate, leading to a cascade of events resulting in tumor necrosis, tumor vasculature shutdown and an anti-tumoral immune attack.

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 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 JX-594 (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 U.S.-based Jennerex Biotherapeutics, Inc., to develop and market JX-594 (TG6006), an oncolytic product. Transgene has bio-manufacturing capacities for viral-based products. Additional information about Transgene is available on the internet at [www.transgene.fr](http://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 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 [www.jennerex.com](http://www.jennerex.com).

**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/TG6006. 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](http://www.transgene.fr) .*

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