



## Transgene and Jennerex Announce First Patient Treated in Phase 1/2 Clinical Trial of JX594/TG6006 in Combination with Chemotherapy in Patients with Metastatic Colorectal Cancer

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**San Francisco, California and Strasbourg, France, March 20, 2010** - 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 the first patient has been treated in a Phase 1/2 clinical trial of JX594 in patients with whose metastatic colorectal cancer has become refractory to chemotherapy and who are either refractory to or ineligible for a treatment with cetuximab<sup>1</sup>. The two-arm, dose-escalation study will evaluate JX594/TG6006 as a monotherapy and in combination with irinotecan<sup>2</sup>.

The multicenter study is conducted in the United States, Canada and Europe and is designed to enroll up to 42 patients. Patients will be enrolled in consecutive dose-escalation cohorts testing two types of administration of JX594/TG6006: either JX594/TG6006 as a monotherapy or JX594/TG6006 in combination with standard dose irinotecan. Patients in both groups will receive five weekly intravenous infusions of JX594/TG6006 followed, at the investigator's option, by up to three intratumoral injections of JX594/TG6006 into metastases to the liver. The combination group will receive concomitant administrations of irinotecan. Once the maximum tolerated dose is determined for each treatment group, additional patients will be enrolled at that dose level. The endpoints of the trial include safety, dose optimization, and tumor responses as measured by RECIST and Choi criteria. For more information about the trial, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

*"JX594/TG6006, with its three diverse, anticancer mechanisms of action, has shown very strong clinical data to date against multiple tumor types, and it is currently being evaluated in clinical trials for advanced liver and colorectal cancers,"* said David H. Kirn, M.D., President and Chief Medical Officer of Jennerex. *"In the clinical trial announced today, we are particularly interested in observing the effects of the combination of JX594/TG6006 with irinotecan given that, in pre-clinical studies, JX594/TG6006 has been shown to sensitize tumors to irinotecan and to have the potential to increase the chemotherapy's anti-tumor effect in colorectal and other cancers."*

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<sup>1</sup> Cetuximab is a murine humanized monoclonal antibody that blocks the epidermal growth factor receptor (EGFR) which is over expressed at the tumor cell's surface. Cetuximab is used in association with chemotherapy to treat metastatic colorectal cancer and in association with radiotherapy for the treatment of head and neck cancer. Cetuximab, or C225, is manufactured by ImClone and marketed by Merck Serono under the brand Erbitux®.

<sup>2</sup> Irinotecan (Campto™) is a semi-synthetic derivative of camptothecin. Associated to cetuximab, irinotecan is indicated for the treatment of patients with metastatic colorectal cancer expressing EGFR who failed chemotherapy with irinotecan.

## **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 1 and Phase 2 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 130 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 safety profile to date with predictable and generally mild side effects that typically include flu-like symptoms that resolve in 24 to 48 hours.

### **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 1/2 clinical trial in CRC, the Company's lead product JX594/TG6006 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 JX594/TG6006 have shown its ability to selectively target a variety of common cancer tumor 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 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](http://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 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](http://www.transgene.fr).

**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 JX594/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).*

**Contacts:**

Philippe Archinard, Chairman & CEO  
+33 (0)3 88279122

Stéphane Boissel, EVP and CFO

Elisabetta Castelli, Director IR  
+33 (0)1 44085505

**MC Services**

Raimund Gabriel  
+49 89 210 228 30

Shaun Brown  
+44 207 148 5998