Transgene Announces Completion of Enrollment in TRAVERSE, a Phase 2b Clinical Trial of Pexa-Vec for the Treatment of Liver Cancer

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Strasbourg, France, May 21, 2013 — Transgene SA (Euronext Paris: TNG), a biopharmaceutical company that develops targeted immunotherapy products to treat major unmet medical needs in cancer and chronic infectious diseases, today announced completion of enrollment in the 120-patient TRAVERSE study. This study is a global randomized phase 2b clinical trial evaluating the efficacy and safety of Pexa-Vec (JX-594/TG6006, pexastimogene devacirepvec) for the treatment of advanced primary liver cancer (hepatocellular carcinoma, HCC) in patients who failed prior therapy with sorafenib (Nexavar®). Pexa-Vec is an investigational oncolytic immunotherapy designed to 1) rapidly de-bulk tumors via tumor cell lysis, 2) induce a durable immune response against tumors, and 3) selectively target tumor vasculature resulting in a rapid reduction in tumor blood flow.

"Completion of enrollment in TRAVERSE represents another important milestone for Pexa-Vec's development," said Philippe Archinard, Chairman and CEO of Transgene. *"We expect top line data from the primary analysis of TRAVERSE in Q4 of this year. These data, together with data from other ongoing trials with Pexa-Vec, should enable us to determine the optimal phase 3 trial design."*

The primary objective of TRAVERSE is to determine the overall survival for patients receiving Pexa-Vec with best supportive care, compared to those receiving best supportive care alone. The study enrolled 120 patients and is being conducted at approximately 40 sites in North America, South Korea, Taiwan, Hong Kong, and Europe.

Previous Phase 2a Study Results:
Data from a previous phase 2 clinical trial using Pexa-Vec to treat liver cancer was recently published in Volume 19, Issue 2 of *Nature Medicine* in February of 2013. In this study, thirty patients were randomized into the low and high dose groups and received three Pexa-Vec treatments over the course of four weeks. The results demonstrated that Pexa-Vec was able to significantly prolong overall survival with 14.1 months median survival for the high-dose group compared to 6.7 months for the low-dose group (p-value = 0.02). The data further demonstrated that Pexa-Vec treatment at both doses resulted in a reduction in tumor size and decreased blood flow in tumors. Induction of an immune response against the tumor, evidenced by antibody-mediated tumor cell toxicity, was also observed. Pexa-Vec was well-tolerated at both high and low doses with the most frequent adverse events consisting of flu-like symptoms lasting less than 24 hours. This was the first randomized clinical trial of an oncolytic immunotherapy demonstrating significantly prolonged overall survival.

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.[i] 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[ii]. Currently, there are few approved treatment options for advanced HCC patients.

About Pexa-Vec:
Pexa-Vec (JX-594/TG6006, pexastimogene devacirepvec) was derived from vaccinia, which has been used for decades as a vaccine in healthy individuals, and was engineered to selectively target cancer cells. Pexa-Vec was also engineered to express GM-CSF, a white blood cell growth factor, which activates a systemic immune response to kill tumor cells throughout the body. Pexa-Vec exploits the unique characteristics of vaccinia, including its stealth extracellular enveloped form, which allows the virus to survive in the bloodstream in the presence of neutralizing antibodies, leading to its ability to be administered both intravenously (IV) and intratumorally (IT). Unlike many targeted therapies that rely on a single target, Pexa-Vec is applicable to multiple solid tumor types.

In addition to TRAVERSE, Pexa-Vec is currently being evaluated as monotherapy in sorafenib-naïve HCC patients and in combination with sorafenib. Pexa-Vec is also being evaluated in a phase 1/2 clinical trial in patients with treatment-refractory colorectal cancer as monotherapy and in combination with irinotecan, and in a Phase 2a clinical trial in treatment-refractory kidney cancer patients.

Phase 1 and phase 2 clinical trials in multiple cancer types to date have shown that Pexa-Vec, delivered either directly into tumors or intravenously, induces tumor shrinkage and/or necrosis and is well-tolerated (over 230 patients treated to date). Objective tumor responses have been demonstrated in a variety of cancers including liver, colon, kidney, lung cancer and melanoma. Pexa-Vec has had a predictable and manageable safety profile to date which includes flu-like symptoms that resolve in 24 hours.

Pexa-Vec is developed by Jennerex, Inc. of San Francisco, California in collaboration with Transgene SA, Green Cross Corporation and Lee's Pharmaceutical Holdings, each with exclusive rights to its territories. Transgene has development and commercialization rights in Europe, CIS and certain North African and Middle Eastern countries, a total of 54 countries.

About Transgene:
Transgene (NYSE-Euronext: TNG), a member of the Institut Mérieux Group, is a biopharmaceutical company. We create, develop and manufacture targeted immunotherapeutics for the treatment of cancers and infectious diseases. Our products are major technological breakthroughs that use well tolerated viruses to indirectly or directly kill infected or cancerous cells. Our four most advanced products have generated proof of concept data in randomized clinical studies: in lung cancer (TG4010), liver cancer (Pexa-Vec), hepatitis C (TG4040) and HPV-related cervical lesions (TG4001). We have concluded strategic agreements for the development of three of these products: an option agreement with Novartis for the development of TG4010, an in-licensing agreement with US-based Jennerex, Inc. to develop and market Pexa-Vec and a strategic collaboration with EORTC to develop TG4001 in cancer of the oropharynx. We also have a non-exclusive agreement with Sanofi/Genzyme for the future commercial production of our products. Most of our 280 employees are based in Strasbourg, France, and we have operations in Lyon, China and the USA. Additional information about Transgene is available at www.transgene.fr.

Transgene Forward Looking Statements:
This press release contains forward-looking statements notably referring to the development of Pexa-Vec as a treatment against HCC. Such anticipated development is based on the results obtained thus far in clinical trials. These results are not necessarily predictive of the results that we may obtain in ongoing or future clinical testing. We could never be able to develop, manufacture or sell Pexa-Vec in the future. 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 on Transgene's website at www.transgene.fr.

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[i] http://www.who.int/mediacentre/factsheets/fs297/en/

[ii] Ferlay J, Shin HR, Bray F, Forman D, Mathers C and Parkin DM.
GLOBOCAN 2008 v2.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 10 [Internet]. Lyon, France: International Agency for Research on Cancer; 2010. Available from: http://globocan.iarc.fr, accessed on day/month/year.