

# Transgene Announces that Clinical Data with Pexa-Vec will be Presented at the 2013 American Society of Clinical Oncology Annual Meeting

Strasbourg, France, May 15, 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 that data relating to Pexa-Vec (JX-594; pexastimogene devacirepvec), an oncolytic virus developed to treat cancers, was featured in three separate abstracts during the American Society of Clinical Oncology (ASCO) Annual Meeting taking place in Chicago, Illinois, May 31 to June 4, 2013. Details of the presentations follow:

- Abstract #3608, Poster: Phase 1b Dose-Escalation Study of Pexa-Vec (*pexastimogene devacirepvec*; JX-594), an Oncolytic and Immunotherapeutic Vaccinia Virus, Administered by Intravenous (IV) Infusions in Patients with Metastatic Colorectal Carcinoma (mCRC). June 2, 2013 8:00 am, Location S Hall A2.
- Abstract #4122, Poster: Phase 2 Trial of Pexa-Vec (*pexastimogene devacirepvec*; JX-594), an Oncolytic and Immunotherapeutic Vaccinia Virus, followed by Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC). June 2, 2013 8:00 am, Location S Hall A2.
- Abstract #TPS4161 (Trials in Progress), Poster: Phase 2b Randomized Trial of Pexa-Vec (pexastimogene devacirepvec; JX-594), a Targeted Oncolytic Vaccinia Virus, plus Best Supportive Care (BSC) Versus BSC Alone in Patients With Advanced Hepatocellular Carcinoma Who Have Failed Sorafenib Treatment (TRAVERSE). June 2, 2013 8:00 am, Location S Hall A2.

Last week, Pexa-Vec was granted the Orphan Drug Status to treat hepatocellular carcinoma by the FDA, a status the oncolytic virus already has in Europe.

"In addition to last week's FDA orphan-drug designation for Pexa-Vec in HCC, the ASCO abstracts continue to set the stage for an important year for Pexa-Vec as we await top line data from various ongoing clinical trials. They also show the potential of this product candidate in the treatment of other tumor types, including colorectal cancer" said Philippe Archinard, Chairman & Chief Executive Officer of Transgene.

#### **About Pexa-Vec**

Pexa-Vec (JX-594, pexastimogene devacirepvec) is an investigational oncolytic immunotherapy designed to 1) rapidly de-bulk tumors via direct killing of tumor cells 2) induce a systemic anti-tumor immune response and 3) selectively target tumor vasculature resulting in a rapid reduction in tumor blood flow. Pexa-Vec was derived from vaccinia vaccine, which has been used for decades as a vaccine in healthy individuals. 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.

Pexa-Vec is currently being evaluated in an international, randomized phase 2b clinical trial (TRAVERSE) in patients with advanced primary liver cancer who have failed sorafenib therapy. It is also being tested as monotherapy in sorafenib-naïve HCC patients and in combination with sorafenib. In addition, Pexa-Vec is 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 (about 250 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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