



## Transgene Announces that its Phase 2 study of Pexa-Vec in Second-line Advanced Liver Cancer did not Meet its Primary Endpoint

- *Conducting additional analyses of data, continuing to advance clinical trials in other cancers*
- *Announcing decision on Phase 3 development in HCC in Q4*

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**Strasbourg, September 3, 2013** — Transgene SA (Euronext Paris: FR0005175080) today announced that TRAVERSE, a randomized Phase 2b study of Pexa-Vec in second-line, advanced liver cancer patients had reached the pre-specified number of events for analysis. The study failed to meet its primary endpoint of overall survival for Pexa-Vec plus best supportive care (BSC) compared to BSC. Pexa-Vec was generally well tolerated with an adverse event profile consistent with previous Pexa-Vec studies in patients with advanced HCC. Additional analyses will be conducted to further understand these data.

*"The rapid progression in this devastating and heterogeneous disease setting has been a longstanding challenge for developing new therapies in liver cancer,"* said Tony Reid, MD, PhD, TRAVERSE investigator and professor of clinical medicine, division of hematology-oncology, UC San Diego Moores Cancer Center. He added: *"Despite the disappointing outcome on the primary endpoint, the TRAVERSE study was well-conducted and no unexpected safety issues were observed. The field of oncolytic immunotherapy, including Pexa-Vec, continues to hold great promise for physicians and patients."*

*"It is a disappointment that TRAVERSE did not reach its primary survival endpoint for this population of patients who have so limited treatment options"* said Philippe Archinard, Chairman and CEO of Transgene. He added: *"A detailed analysis of the final results of TRAVERSE along with other ongoing studies will be conducted by the end of the year. At this stage, the decision to move Pexa-Vec into Phase 3 in first line HCC next year is still expected to be made in Q4 2013".*

Besides the TRAVERSE trial, Pexa-Vec is currently being evaluated in kidney, colorectal, and ovarian cancers through 4 other ongoing clinical studies (see About Pexa-Vec).

Transgene will hold a conference call today, September 3, 2013, at 6:45 pm CET. To listen the conference in live or on demand, please click on the following link :

<http://www.media-server.com/m/p/92db82hk>

If you want to ask us questions during the questions and answers session, please dial :

US: +1 646 254 3363 - Confirmation code 5562667

UK : +44 (0)20 3427 1911 - Confirmation code 5562667

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

Pexa-Vec (JX-594, 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 and in an exploratory study in ovarian cancer.

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 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 generally 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](http://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 certain cancers. 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](http://www.transgene.fr).*

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