

## Transgene Announces Poster Presentation at ASCO Annual Meeting on the Phase 3 PHOCUS Clinical Trial with Pexa-Vec Oncolytic Immunotherapy

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**Strasbourg, France, May 31, 2016, 6:00 pm CET** – Transgene (Euronext Paris: TNG), a company focused on designing and developing targeted immunotherapies for the treatment of cancer and infectious diseases, today announced that a poster on the ongoing Pexa-Vec Phase 3 trial in first line advanced HCC patients will be presented at the American Society of Clinical Oncology (ASCO) Meeting on June 4<sup>th</sup>, in Chicago, IL, USA.

**Date and Time:** Saturday, June 4, 2016, 8:00 a.m. – 11:30 a.m. CDT

**Abstract Title:** PHOCUS: A Phase 3 randomized, open-label study comparing the oncolytic immunotherapy Pexa-Vec followed by Sorafenib (SOR) vs SOR in patients with advanced hepatocellular carcinoma (HCC) without prior systemic therapy.

**Abstract Number:** TPS4146

**Location:** Hall A

**Poster Board:** #130b

**Poster Session:** Gastrointestinal (Noncolorectal) Cancer

**Presenter:** Ghassan K. Abou-Alfa, MD - Memorial Sloan Kettering Cancer Center

**NCT02562755**

The abstract is available via the following link:

[http://abstract.asco.org/176/AbstView\\_176\\_164722.html](http://abstract.asco.org/176/AbstView_176_164722.html)

### **PHOCUS trial: study initiated in January 2016 in HCC and actively recruiting**

The PHOCUS clinical trial is a multinational, randomized Phase 3 open label study with the oncolytic immunotherapy, Pexa-Vec, in patients with advanced liver cancer, also known as hepatocellular carcinoma (HCC). This trial is being led by Transgene's partner, SillaJen, Inc. The trial is evaluating the use of Pexa-Vec to treat HCC patients who are eligible for treatment with sorafenib (Nexavar®), the only approved drug for advanced HCC.

The study is designed to enroll 600 patients who have not received prior systemic treatment for their cancer. Patients will be randomized 1:1 to one of two treatment groups: one which will receive Pexa-Vec followed by sorafenib and one which will receive sorafenib alone. The study will be conducted at approximately 140 sites worldwide, including in North America, Asia, Australia and Europe. SillaJen, Inc. reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for this global Phase 3 clinical trial. The primary endpoint of the study is overall survival. Secondary objectives include safety, as well as assessments for tumor responses between the two groups as measured by the following endpoints: time to progression, progression-free survival, overall response rate and disease control rate. To learn more about the trial, please visit <https://www.clinicaltrials.gov/ct2/show/NCT02562755?term=JX594&rank=15> or [www.pexavectrials.com](http://www.pexavectrials.com).

### **About HCC (Hepatocellular carcinoma)**

According to recent statistics (GLOBOCAN 2012), there were over 780,000 new cases of liver cancer worldwide in 2012 and over 745,000 deaths due to this disease. In Europe, there were estimated to be over 63,000 new cases and over 62,000 deaths from liver cancer. In the U.S., according to the American Cancer Society, over 35,000 new cases of liver cancer were expected to be diagnosed in 2015 and 24,000 deaths projected from the disease. Hepatocellular carcinoma is estimated to account for over 80% of all liver cancer. Currently there are few treatment options for advanced HCC patients, with only one drug, sorafenib, approved for the treatment of HCC. With a low five-year survival rate, especially for patients diagnosed at later stages of disease, and limited available therapies, new treatments are urgently needed.

### **About Pexa-Vec**

Pexa-Vec (pexastimogene devacirepvec) is an oncolytic immunotherapy armed with a GM-CSF gene that promotes an anti-tumor immune response. Pexa-Vec is designed to selectively target and destroy cancer cells through three different mechanisms of action: the lysis (breakdown) of cancer cells through viral replication, the reduction of the blood supply to tumors through vascular disruption, and the stimulation of the body's immune response against cancer cells. The lead indication for Pexa-Vec is hepatocellular carcinoma (HCC, liver cancer); trials in other cancer types are underway or planned.

SillaJen, Inc. has partnered with Transgene and Lee's Pharmaceutical to develop and commercialize Pexa-Vec in major markets outside of the United States. Transgene has exclusive rights to develop and commercialize Pexa-Vec for the treatment of solid tumors in Europe, while Lee's Pharmaceutical retains exclusive development and commercial rights in Hong Kong and The People's Republic of China.

### **About SillaJen, Inc., Transgene's Partner for Pexa-Vec**

SillaJen, Inc. is a private, South Korean based biotechnology company headquartered in Busan South Korea, with satellite offices in Seoul, South Korea and San Francisco, CA. The company is focused on the development and commercialization of oncolytic immunotherapy products using the SOLVE™ platform, including its lead product Pexa-Vec, which is currently in Phase 3 trials for the treatment of advanced primary liver cancer. Additional information about SillaJen is available at [www.sillajen.com](http://www.sillajen.com).

### **About Transgene**

Transgene S.A. (Euronext: TNG), part of Institut Mérieux, is a publicly traded French biopharmaceutical company focused on designing and developing targeted immunotherapies for the treatment of cancer and infectious diseases. Transgene's programs utilize viral vector technology with the goal of indirectly or directly killing infected or cancerous cells. The Company's two lead clinical-stage programs are: TG4010 for non-small cell lung cancer and Pexa-Vec for liver cancer. The Company has several other programs in clinical and pre-clinical development. Transgene is based in Strasbourg, France, and has additional operations in Lyon, as well as satellite offices in China and the U.S. Additional information about Transgene is available at [www.transgene.fr](http://www.transgene.fr).

### **Disclaimer**

*This press release contains forward-looking statements about the future development of Pexa-Vec. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results and development. The Company's ability to commercialize its products depends on but is not limited to the following factors: positive pre-clinical data may not be predictive of human clinical results, the success of clinical studies, the ability to obtain financing and/or partnerships for product development and commercialization, and marketing approval by government regulatory authorities. For a discussion of*

*risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Document de Référence, which is available on the AMF website (<http://www.amf-france.org>) or on Transgene's website ([www.transgene.fr](http://www.transgene.fr)).*

*Nexavar® is a registered trademark of Bayer HealthCare Pharmaceuticals, Inc.*

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