# Transgene and SillaJen Announce Revised Agreement for Pexa-Vec Oncolytic Viral Therapy and Provide Update on Clinical Development

- ***Phase 3 trial in liver cancer on track to start this quarter***
- ***Two exploratory trials have been initiated***
- ***Combination trials with immune checkpoint inhibitors planned to start in 2016***

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**Strasbourg, France, November 12, 2015 –** Transgene SA (Euronext: TNG) and SillaJen, Inc. today announced that they have signed an amended agreement for the development and commercialization of oncolytic viral therapy Pexa-Vec to streamline the conduct of clinical trials and to reflect important areas of interest for each company. Key changes to the agreement are outlined below.

*1) Management and funding of the Phase 3 trial (PHOCUS) in hepatocellular carcinoma (HCC).* SillaJen will assume responsibility for conducting the trial. Transgene remains responsible for submitting for marketing approval and retains commercialization rights in its territories. In return, Transgene will pay a total of $6 million to SillaJen over four years beginning this year. Under the terms of the original contract, Transgene was responsible for the development costs in its licensed territories.

*2) Redefined territories.* Transgene has returned rights to SillaJen for all Middle Eastern countries, Russia, Ukraine, Belarus and Turkey. This change enables Transgene to focus on Europe, its core area of interest, while returning to SillaJen markets that provide additional commercialization opportunities.

*3) Initiation and funding of key exploratory combination trials.* Under the amended agreement, Transgene has committed to initiate independently an exploratory trial evaluating Pexa-Vec in combination with nivolumab for the treatment of HCC. Transgene will be responsible for all costs related to this trial, as well as any other exploratory trials it independently initiates.

"Our amended agreement provides us and our partner an opportunity to expand development options for Pexa-Vec while maintaining progress in our pivotal Phase 3 clinical trial. We look forward to continue working toward successful development of Pexa-Vec for cancer patients with our partnership," stated Eun Sang Moon, Chief Executive Officer of SillaJen.

Philippe Archinard, Chairman and Chief Executive Officer of Transgene, said: "We are very pleased to have signed this amended agreement with our partner, SillaJen. We believe this is a win-win situation for the two companies, enabling us to move forward in evaluating Pexa-Vec in different cancer types and in combination with other therapies. With the first oncolytic viral therapy recently receiving marketing approval in the U.S., this has become an important area of immunotherapy development. We are excited about the opportunity Pexa-Vec holds for treating advanced cancer patients and look forward to initiating new studies with this promising therapeutic candidate."

The companies also outlined key parts of the current clinical development plan for Pexa-Vec.

*Phase 3 trial in HCC expected to initiate soon.* The Phase 3 trial of Pexa-Vec, named PHOCUS, followed by sorafenib in the first-line treatment of patients with advanced HCC, the most common form of liver cancer, is on track to initiate in the fourth quarter of this year. Sorafenib is currently the only approved treatment for this disease, and new therapies are urgently needed. The trial is being led by SillaJen and is planned to enroll approximately 600 patients in North America, Europe and Asia. The study is being conducted under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA).

*Ongoing and planned exploratory trials.* Transgene is independently conducting several exploratory studies with Pexa-Vec. Two trials in combination with immune checkpoint inhibitors are being planned and are expected to initiate during 2016: a study with nivolumab in advanced HCC and another with ipilimumab in advanced melanoma. Two other studies are underway and patients have been dosed: 1) a study evaluating Pexa-Vec in combination with metronomic cyclophosphamide, a drug used in combination with other therapies to treat a wide variety of cancers, mainly in patients with advanced breast cancer or soft tissue sarcoma, is being sponsored by the Bergonié Institute (Bordeaux, France); and 2) a study evaluating Pexa-Vec in cancer patients in the pre-surgery (neoadjuvant) setting to further document the mechanism of action of Pexa-Vec is being sponsored by the University of Leeds (Leeds, United Kingdom).

***About Pexa-Vec***

Pexa-Vec (JX594/TG6006 pexastimogene devacirepvec) is an oncolytic viral therapy 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.

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.

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***

SillaJen, Inc. is a private, South Korea 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 proprietary SOLVE$^{TM}$ platform, including its lead product Pexa-Vec for the treatment of advanced primary liver cancer. Additional information about SillaJen is available at www.sillajen.com.

***About Transgene***

Transgene S.A. (Euronext: TNG), part of Institut Mérieux, is a publicly traded French biopharmaceutical company focused on discovering 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.

***About Lee's Pharma***

Lee's Pharmaceutical Holdings Limited is a research-based biopharmaceutical company listed in Hong Kong with over 20 years operation in China's pharmaceutical industry. It is fully integrated with strong infrastructures in drug development, manufacturing, sales and marketing. It has established extensive partnership with over 20 international companies and currently has 14 products in the market place. Lee's focuses on several key disease areas such as cardiovascular, oncology, gynecology, dermatology and ophthalmology. Lee's development program is lauded with 47 products stemming from both internal R&D efforts and collaborations with US, European and Japanese companies and aspiring to combat diseases such as liver cancer and pulmonary hypertension. The mission of Lee's is to become a successful biopharmaceutical group in Asia providing innovative products to fight diseases and improve health and quality of life. Additional information about Lee's Pharmaceutical is available at www.leespharm.com.

***Disclaimer for Transgene:***

*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).*

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