



Global Partners SillaJen, Transgene and Lee's Pharmaceutical Confirm Clinical Development Plan for Pexa-Vec

- Enrollment of Phase 3 study in first-line advanced liver cancer expected to begin by mid-2015
 - To initiate several additional Phase 1/2 trials during 2014

Busan, South Korea; San Francisco, CA, USA; Strasbourg, France and Hong Kong, March 26, 2014 – Transgene SA (NYSE-Euronext: TNG), Lee's Pharmaceutical (HKEx: 0950) and SillaJen today unveiled their late-stage clinical development plan for Pexa-Vec (JX-594/TG6006) oncolytic immunotherapy. The companies plan to initiate a global Phase 3 study in the first-line treatment of advanced hepatocellular carcinoma (HCC, liver cancer) patients, as well as several additional Phase 1/2 trials in different cancers, both as a single agent and in combination with a variety of other treatments, including immunotherapies such as immune checkpoint inhibitors. In addition, the partners plan to undertake several exploratory trials of intravenous infusion therapy in various tumor types, including renal, breast and soft tissue sarcoma.

Dr. Eun-Sang Moon, CEO of SillaJen, Inc. said: "With the recent closing of our acquisition of Jennerex, Inc., we are very excited to focus, together with Transgene and our other partners, on advancing and broadening the clinical development for Pexa-Vec, our innovative oncolytic immunotherapy. We believe that this emerging multi-mechanistic therapeutic class holds great promise in treating patients with cancers for which today there are very limited treatment options. In a dose-finding Phase 2 study, Pexa-Vec has demonstrated clinical activity with IV delivery. High-dose Pexa-Vec was associated with longer survival benefit in first-line liver cancer patients in Phase 2b, as published in Nature Medicine."

Philippe Archinard, Chairman and Chief Executive Officer of Transgene, said: "Together with SillaJen and our other partners, we are pleased to be moving forward our joint development plan for Pexa-Vec. Pexa-Vec is an oncolytic immunotherapy with therapeutic potential, we believe, in several hard-to-treat cancers. In addition to moving the program into Phase 3 testing in liver cancer, for which today there is only one approved product, we will be exploring its potential in other cancer types and in combination with other therapies, such as immune checkpoint inhibitors."

Dr. Benjamin Li, Chief Executive Officer of Lee's Pharmaceutical, said: "China has the highest prevalence in liver cancer (HCC) in the world and despite recent advancement in targeted therapy, significant medical need remains unmet. Pexa-Vec's oncolytic immunotherapy approach has been shown in a previous Phase 2 study as a promising first line treatment option for advanced liver cancer patients. We look forward to starting the Phase 3 clinical trial with our partners in 2015 to validate the potential of this exciting agent and work towards a better management of advanced HCC in China."

To date, over 300 patients have been treated with Pexa-Vec. Additional data supporting the activity of Pexa-Vec across different tumor types is expected to be presented at upcoming medical conferences later this year.

Lead Program - The planned Phase 3 trial will assess Pexa-Vec followed by sorafenib in the first-line treatment of patients with advanced HCC. This global study will be conducted in Europe, Asia and North America. It is expected to enroll approximately 600 patients. Patients will be randomized 1:1 to either receive Pexa-Vec immediately followed by sorafenib or to receive sorafenib alone. Sorafenib (Nexavar[®]) is currently considered the global standard of care and is the only product approved for the first-line treatment of advanced HCC. The study is expected to start recruitment by mid-2015.

Additional Studies - In addition and as previously announced, a study evaluating Pexa-Vec and metronomic doses of cyclophosphamide in solid tumors, mainly in breast cancer and soft tissue sarcoma, is planned to be initiated this year. The study is being funded by the Institut National du Cancer (INCa) and sponsored by the Bergonié Institute (Bordeaux, France). Cyclophosphamide given at metronomic doses is used classically in combination with immunotherapeutics to potentiate their activity.

Other trials to complement and strengthen the program are also planned and include:

- A trial in the pre-surgery (neo-adjuvant) setting in solid tumors to gain a better understanding of Pexa-Vec activity in the actual tumor environment.
- A trial evaluating Pexa-Vec in combination with an immune checkpoint inhibitor, based on the rationale of gaining synergy and potency in combining two immunotherapy classes. This type of combination approach holds high promise in oncology.

The partners are also considering a Phase 1/2 study in combination with sunitinib malate (Sutent[®]) for renal cell cancer.

Commented Dr. Tae-Ho Hwang, SillaJen co-founder and Chief Scientific Officer: "We anticipate a number of these early exploratory studies will be performed in collaboration with Pusan National University Yangsan Hospital (PNUYH). The excellent team at PNUYH has been very supportive of the Pexa-Vec program and has demonstrated an ability to enroll patients quickly and conduct studies efficiently. We believe open collaboration and innovation by both the Company and Hospital is very important to lead promising immunotherapeutics such as Pexa-Vec to the clinic and we look forward to building on this progress as we move forward."

About Pexa-Vec

Pexa-Vec (JX594/TG6006 pexastimogene devacirepvec) is an engineered oncolytic vaccinia virus 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. Clinical trials are ongoing or planned in hepatocellular carcinoma (liver cancer), renal cell carcinoma (kidney cancer), as well as other tumor types.

Hepatocellular carcinoma, the lead indication for Pexa-Vec, 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.

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

About SillaJen, Inc.

SillaJen, Inc., headquartered and with research laboratories in Busan, South Korea with offices in San Francisco, California, is an R&D company specializing in the translational and clinical development of complex biologics. Headquartered on the campus of Pusan National University, the company is comprised of dedicated in-house pre-clinical, bioanalytic, and clinical research teams that collaborate closely with a network of local hospitals (including PNUYH) and USA-based world-class scientists and physicians. Born from a desire to revolutionize therapeutic approaches for patients with serious unmet medical needs and honed through years of pioneering experience guiding oncolytic vaccinia through clinical trials in Korea, the SillaJen operations are uniquely poised for rapid and efficient development of similar cutting-edge gene and viral therapies. Additional information about SillaJen can be found at www.sillajen.com.

About Transgene

Transgene (NYSE-Euronext: TNG), a member of the Institut Mérieux Group, is a publicly traded French biopharmaceutical company focused on discovering, developing and manufacturing targeted immunotherapies for the treatment of cancer and infectious diseases. Transgene's programs utilize well-tolerated viruses with the goal of indirectly or directly killing infected or cancerous cells. The Company's four clinical-stage programs are: TG4010 for non-small cell lung cancer; Pexa-Vec for liver cancer; TG4001 for oropharyngeal cancer (under a collaboration agreement with the EORTC) and TG4040 for chronic Hepatitis C. Transgene has concluded corporate strategic agreements for the development of two of its immunotherapy products: an exclusive option agreement with Novartis for the development and commercialization of TG4010 and an in-licensing agreement with U.S.-

based Jennerex, Inc. for the development and commercialization of Pexa-Vec in certain territories. The Company also has several programs in research and pre-clinical development that are based on its core viral vector technology. 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.

Transgene Disclaimer

This press release contains forward-looking statements about the future development of the Pexa-Vec program. 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 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).

About Lee's Pharmaceutical

Lee's Pharmaceutical Holdings Limited is a research-based Hong Kong biopharmaceutical company with 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 30 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 <u>www.leespharm.com</u>.

Lee's Pharmaceutical Safe Harbor Statement

The performance and the results of operation of Lee's during the past years are historical in nature and past performance can be no guarantee of future results of the Lee's. This news release may contain forward-looking statements and opinions that involve risks and uncertainties. Actual results may differ materially from expectations discussed in such forward-looking statements and opinions. Neither Lee's nor the Directors, employees or agents of Lee's assume (a) any obligation to correct or update the forward-looking statements or opinions contained in this news release; and (b) any liability in the event that any of the forward-looking statements or opinions does not materialize or turns out to be incorrect.

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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: <u>http://globocan.iarc.fr</u>

Nexavar $^{\mbox{\ensuremath{\mathbb{R}}}}$ is a registered trademark of Bayer HealthCare Pharmaceuticals, Inc. Sutent $^{\mbox{\ensuremath{\mathbb{R}}}}$ is a registered trademark of Pfizer.