Agreement with FDA Announced for Special Protocol Assessment for Upcoming Phase 3 Pexa-Vec Trial in Advanced Liver Cancer

Strasbourg, France, April 16, 2015 – Transgene SA (Euronext: TNG) reported today that an agreement has been reached with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for the global Phase 3 clinical trial of the oncolytic immunotherapy, Pexa-Vec. The SPA now enables Transgene, SillaJen, Inc. and the other global partners for Pexa-Vec to have clarity on the acceptability of the global Phase 3 study. The pivotal trial will evaluate the use of Pexa-Vec to treat patients with advanced liver cancer, also known as hepatocellular carcinoma (HCC), who have not received sorafenib (Nexavar®) therapy and is expected to begin enrollment later this year.

"We are eagerly looking forward to the initiation of this trial of Pexa-Vec in patients with incurable liver cancer. Cancer immunotherapy is making a significant impact across multiple cancer types and we hope this trial will help bring a novel immunotherapy to liver cancer patients, particularly given the limited viable treatment options available to this patient population," said Ghassan Abou-Alfa, medical oncologist at Memorial Sloan Kettering Cancer Center and lead investigator on the Phase 3 trial.

The Phase 3 clinical trial is designed to enroll 600 patients with advanced liver cancer who are eligible to receive sorafenib therapy. The randomized study will be conducted at approximately 120 sites worldwide including North America, Asia, and Europe. The primary objective of the trial is to determine the overall survival benefit for patients receiving Pexa-Vec followed by sorafenib, compared to sorafenib alone in patients with advanced liver cancer.

About Pexa-Vec

Pexa-Vec is an oncolytic immunotherapy that utilizes the vaccinia poxvirus strain as its backbone. This strain has been used safely in millions of people as part of a worldwide vaccination program. This strain naturally targets cancer cells due to common genetic defects in cancer cells; Pexa-Vec was engineered to enhance this by deleting its thymidine kinase (TK) gene, thus making it dependent on the cellular TK expressed at persistently high levels in cancer cells. Pexa-Vec is also engineered to express the immunogenic GM-CSF protein. GM-CSF complements the cancer cell lysis of the product candidate, leading to a cascade of events resulting in tumor necrosis, tumor vasculature shutdown and sustained anti-tumoral immune attack.

Transgene has an exclusive license from SillaJen, Inc. to develop and commercialize Pexa-Vec for the treatment of solid tumors in Europe, the Commonwealth of Independent States and the Middle East. Under the terms of the agreement, Transgene is responsible for clinical development, pursuant to the Pexa-Vec global development plan, and commercialization in its licensed territories. SillaJen's other regional partners for Pexa-Vec are Green Cross Corp. and Lee's Pharmaceutical Holdings Limited.

About SillaJen

SillaJen, Inc. is a 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 the 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 Green Cross Corp.

Green Cross Corp. is a publicly traded and leading Korean biopharmaceutical company specialized in development and commercialization of vaccines, plasma-derivatives, recombinant proteins and therapeutic antibodies in oncology and infectious diseases. Green Cross is well-renowned for its competitive and broad pipeline of drugs across a wide array of diseases, and harbors fully-integrated biologics capabilities across product development processes in multiple therapeutic areas. Green Cross is highly experienced in collaborative opportunities in out-licensing, co-research, co-development and co-marketing projects with various pharmaceutical companies around the world. Additional information about Green Cross Corp. is available at www.greencross.com.

About Lee's Pharmaceutical Holdings Limited

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.

About Transgene

Transgene (Euronext: TNG), part of Institut Mérieux, 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 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 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.

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 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).

Contacts

Transgene:
Elisabetta Castelli, Director Investor Relations
+33 (0)3 88 27 91 21

Laurie Doyle, Director Investor Relations US & Corporate Communications
+1 (339) 832 0752

investorrelations@transgene.fr

For media: MC Services
Raimund Gabriel
+49 89 210 228 30
raimund.gabriel@mc-services.eu

Shaun Brown
+44 207 148 5998
shaun.brown@mc-services.eu