

Transgene Announces First Patient Randomized in Multinational Phase 3 Trial for Pexa-Vec Oncolytic Immunotherapy in Advanced Liver Cancer

Strasbourg, France, January 6, 2016 – Transgene S.A. (Euronext: TNG) today announced the initiation of 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, named the PHOCUS trial, 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 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 will be overall survival. Secondary objectives will 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 www.clinicaltrials.gov or www.pexavectrials.com.

“The initiation of the Phase 3 trial with Pexa-Vec in patients with advanced liver cancer is an important step forward in the development of this oncolytic immunotherapy,” said Philippe Archinard, Chairman and Chief Executive Officer of Transgene. *“The recent marketing approval of the first oncolytic immunotherapy has paved the way for this promising class of cancer treatments. We look forward to exploring Pexa-Vec’s potential utility in treating advanced liver cancer, as well as other cancer types.”*

“We are pleased to be initiating this multinational Phase 3 trial for Pexa-Vec - an oncolytic immunotherapy which demonstrated antitumor activity in Phase 2 clinical trials for liver cancer,” stated Eun Sang Moon, Chief Executive Officer of SillaJen. *“Our primary focus at this time is to execute a well-run, successful clinical trial, and we believe that the SPA that we have in place with the FDA will allow us and our global partners a clear path to approval for Pexa-Vec.”*

“We are still desperately in need of additional treatment options for advanced liver cancer. Cancer immunotherapy holds much promise, and I’m greatly looking forward to having the opportunity to evaluate Pexa-Vec in patients with advanced liver cancer,” stated Ghassan Abou-Alfa, M.D., medical oncologist at Memorial Sloan Kettering Cancer Center and lead investigator on the Phase 3 trial.

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.

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, 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.

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.

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).

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