SillaJen and Transgene Announce the Enrollment of the First European Patient in Multinational Phase 3 Trial for Pexa-Vec in Advanced Liver Cancer

-Milestone Triggers $4 Million Payment from Transgene to SillaJen-

Seoul, Korea, San Francisco, Calif., and Strasbourg, France - April 24, 2017, 5:45 p.m. CET - SillaJen, Inc., (KOSDAQ:215600), a clinical-stage, biotherapeutics company focused on the development of oncolytic immunotherapy products for cancer, and Transgene (Euronext: TNG), a French biotechnology company focused on discovering and developing immune-targeted immunotherapies for the treatment of cancer and infectious diseases, have enrolled the first European patient in the ongoing multinational randomized Phase 3 open-label study of Pexa-Vec (formerly JX-594), in patients with advanced liver cancer, also known as hepatocellular carcinoma (HCC). The trial is evaluating the use of Pexa-Vec to treat HCC patients who have failed locoregional therapies and are eligible for treatment with sorafenib (Nexavar®), the only approved systemic treatment for advanced HCC. The European patient was enrolled at Azienda Ospedaliero-Universitaria Hospital in Parma, Italy.

The enrollment of the first European patient triggers a $4 million USD milestone to be paid to SillaJen by Transgene.

The study, named the PHOCUS trial, started in January 2016 and is now active in North America, Asia, Australia and Europe. It is designed to enroll 600 patients who have not received prior systemic treatment for their cancer, and they will be randomized to one of two treatment groups: one which will receive Pexa-Vec followed by sorafenib and one which will receive sorafenib alone. The randomized study will be conducted at approximately 140 sites worldwide. 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 objective of the study is to determine the overall survival of patients treated with Pexa-Vec. 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: http://www.pexavectrials.com/.

“We are pleased with the progress in our PHOCUS trial and are happy to report that we are now enrolling patients in 11 countries across the globe,” stated Eun Sang Moon, chief executive officer of SillaJen. “This trial, which is actively enrolling patients with HCC, is being conducted at some of the most highly regarded institutions for cancer in the world, and we are grateful to be working with such an exemplary team of physicians.”
“The enrollment of the first patient in Europe in the PHOCUS trial is an important step forward in the development of Pexa-Vec in association with the current standard of care in advanced liver cancer,” said Philippe Archinard, chairman and chief executive officer of Transgene. “This trial is part of a broad clinical development plan that will allow us to position this promising oncolytic virus in all relevant settings to improve the clinical outcome of patients with advanced solid tumors such as HCC, in which there still is a very high unmet medical need.”

At the Azienda Ospedaliero-Universitaria of Parma, a multidisciplinary team, coordinated by Dr. Gabriele Missale, collaborates to provide the best treatment decisions for patients with HCC. “Indeed we need new options for patients with advanced HCC and the immunotherapeutic approach with Pexa-Vec is a new weapon and a great opportunity for our patients. Having enrolled, here in Parma, the first European patient into the PHOCUS Trial, testifies our commitment to expanding options to fight HCC,” stated Dr. Missale.

Pexa-Vec Clinical Development Program and SOLVE Platform

Pexa-Vec is the most advanced product candidate from SillaJen’s proprietary SOLVE™ (Selective Oncolytic Vaccinia Engineering) platform. The vaccinia strain backbone of Pexa-Vec 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.

About SillaJen’s Regional Partners for Pexa-Vec

About Transgene

Transgene S.A. (Euronext: TNG), part of Institut Mérieux, is a publicly traded French biotechnology company focused on designing and developing immune-targeted viral-based therapies for the treatment of cancers 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, a therapeutic vaccine for non-small cell lung cancer, and Pexa-Vec, an oncolytic virus for liver cancer. The Company has several other programs, including TG4001, in clinical and preclinical development. Transgene is based in Strasbourg, France, and has additional operations in Lyon, as well as a joint venture in China. Additional information about Transgene is available at www.transgene.fr. Follow us on Twitter: @TransgeneSA

About Lee’s Pharmaceutical

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 15 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 over 40 products stemming from both
internal R&D efforts and collaborations with US, European and Japanese companies, including promising compounds to treat 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 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 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.

Disclaimer Language
This press release contains certain forward-looking statements regarding, among other things, statements relating to goals, plans and projections regarding the Company’s financial position, results of operations, market position, product development and business strategy. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and SillaJen undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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