SillaJen and Lee’s Pharmaceutical Announce Approval by the China CFDA to Commence Phase 3 Clinical Trial for Oncolytic Immunotherapy, Pexa-Vec, in Liver Cancer

--Chinese FDA Approves SillaJen Trial in First-Ever Public Forum to Promote Transparency in Drug Approval Process—

Seoul, Korea, San Francisco, California, Hong Kong—July 24, 2017 -- SillaJen, Inc., (KOSDAQ:215600), a clinical-stage, biotherapeutics company focused on the development of oncolytic immunotherapy products for cancer, and Lee’s Pharmaceutical Holdings Ltd. (HKEx:0950), a research based biopharmaceutical company, announced approval (Approval No. 2017L044501) by the China Food and Drug Administration (CFDA) to conduct a Phase 3 clinical trial for advanced liver cancer using its oncolytic immunotherapy called Pexa-Vec (formerly JX-594), the PHOCUS study. SillaJen and Lee’s Pharmaceutical participated in a first of its kind Chinese Center for Drug Evaluation advisory committee meeting for this approval, which was held earlier this year to promote transparency in the China drug development process. At the end of the meeting, the committee voted, and it was announced by the chairman of the advisory committee, that the trial had been approved to be conducted in China.

The PHOCUS trial, is a global Phase 3 study, for 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 in North America, Asia, Australia, and Europe, with China being the most recent addition. The primary objective of the study will be to determine the overall survival of patients treated with Pexa-Vec, followed by sorafenib versus sorafenib alone. To learn more about the trial, please visit: http://www.pexavectrials.com/.

“This is exciting progress and a very important milestone for our Pexa-Vec program” stated Dr. Eun Sang Moon, chief executive officer of SillaJen. “We are keenly aware of the high unmet needs in liver cancer in China, and it is our sincere hope that we will be able to offer Pexa-Vec to these patients in the years ahead.”

“We are glad that the CDE of China CFDA has approved our phase III IND application, and we look forward to enrolling the PHOCUS trial in China. This is an important milestone for Pexa-Vec development, and is a result of our tremendous team work with SillaJen,” stated Dr. Benjamin Li, chief executive officer of Lee’s Pharmaceutical.
Pexa-Vac Clinical Development Program and SOLVE Platform

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

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-Vac 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 Pharm
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 Pharm 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 Pharm 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 Pharm 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-Vac, 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.
Safe Harbor Statement
The statements in this news release, other than the historical financial information, may contain forward-looking statements that involve risks and uncertainties that could cause actual results to differ from anticipated results. Further information on risk factor that could affect, among other things, Lee’s financial condition and results of operations is detailed in Lee’s IPO prospectus, as filed with the Main Board of the Stock Exchange of Hong Kong Limited.

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