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Jennerex and Lee's Pharmaceutical Announce Completion of Enrollment in Phase 2b Clinical Trial of Pexa-Vec for the Treatment of Liver Cancer

San Francisco, Calif. – May 22, 2013 — Jennerex Biotherapeutics, Inc., a private, clinical-stage biotechnology company focused on the development and commercialization of best-in-class targeted oncolytic immunotherapies for solid tumors, today announced that it completed enrollment of 120 patients in the TRAVERSE study, a global randomized Phase 2b clinical trial evaluating the efficacy and safety of Pexa-Vec (JX-594, pexastimogene devacirepvec) for the treatment of advanced primary liver cancer (hepatocellular carcinoma, HCC) in patients who failed prior therapy with sorafenib (Nexavar®). Pexa-Vec, Jennerex's lead product candidate, is an investigational oncolytic immunotherapy designed to 1) rapidly de-bulk tumors via tumor cell lysis, 2) induce a systemic anti-tumor immune response, and 3) selectively target tumor vasculature resulting in a rapid reduction in tumor blood flow.

"We are pleased to have completed enrollment in TRAVERSE, the largest study to date of Pexa-Vec, ahead of schedule," said Laurent Fischer, M.D., president and chief executive officer of Jennerex. "We would like to thank investigators and patients who participated in the study. We believe that physician and patient interest in this trial validates our novel approach to treating HCC and underscores the need for new treatment options for liver cancer, the third most deadly cancer."

The primary objective of TRAVERSE is to determine the overall survival for patients receiving Pexa-Vec with best supportive care, compared to those receiving best supportive care alone. The study enrolled 120 patients and is being conducted at approximately 40 sites in North America, South Korea, Taiwan, Hong Kong, and Europe. For more information about this study, please visit www.traversetrial.com.

“Completion of enrollment on TRAVERSE represents another important milestone for Pexa-Vec development and we expect top-line data from the primary analysis by the end of the year,” said Fischer. “We look forward to advancing Pexa-Vec into Phase 3 trials and the potential of developing a novel therapeutic option with meaningful efficacy.”

“As Jennerex’s local partner in China, we are elated by this monumental achievement for Pexa-Vec (JX-594) development,” commented Dr. Benjamin Li, the Chief Executive Officer of Lee’s Pharmaceutical Holdings Limited. “With the topline data of the Phase 2b study expected at the end of year, we are gearing up our preparation for the Phase 3 pivotal trial of Pexa-Vec, in which China is expected to play an important role.”

Phase 2a Study Results

Data from Jennerex’s Phase 2 clinical trial using Pexa-Vec to treat liver cancer was recently published in Volume 19, Issue 2 of *Nature Medicine* in February of 2013. In this study, 30 subjects were randomized into the low and high dose groups and received three Pexa-Vec treatments over the course of four weeks. The results demonstrated that Pexa-Vec was able to significantly prolong overall survival with 14.1 months median survival for the high-dose group compared to 6.7 months for the low-dose group (p-value = 0.02). The data further demonstrated that Pexa-Vec treatment at both doses resulted in a reduction in tumor size and decreased blood flow in tumors. Induction of an immune response against the tumor, evidenced by antibody-mediated tumor cell toxicity, was also observed. Pexa-Vec was well-tolerated at both high and low doses with the most frequent adverse events consisting of flu-like symptoms lasting less than 24 hours. This was the first randomized clinical trial of an oncolytic immunotherapy demonstrating significantly prolonged overall survival.

Hepatocellular Carcinoma: A Global Unmet Need

Hepatocellular carcinoma 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, respectivelyⁱⁱ. Currently, there are few approved treatment options for advanced HCC patients.

About Pexa-Vec

Pexa-Vec (JX-594, pexastimogene devacirepvec) was derived from vaccinia, which has been used for decades as a vaccine in healthy individuals, and was engineered to selectively target cancer cells. Pexa-Vec was also engineered to express GM-CSF, a white blood cell growth factor, which activates a systemic immune response to kill tumor cells throughout the body. Pexa-Vec exploits the unique characteristics of vaccinia, including its stealth extracellular enveloped form, which allows the virus to survive in the bloodstream in the presence of neutralizing antibodies, leading to its ability to be administered both intravenously (IV) and intratumorally (IT). Unlike many targeted therapies that rely on a single target, Pexa-Vec is applicable to multiple solid tumor types.

In addition to TRAVERSE, Pexa-Vec is currently being evaluated as monotherapy in sorafenib-naïve HCC patients and in combination with sorafenib. Pexa-Vec is also being evaluated in a Phase 1-2 clinical trial in patients with treatment-refractory colorectal cancer as monotherapy and in combination with irinotecan, and in a Phase 2a clinical trial in treatment-refractory kidney cancer patients.

Phase 1 and Phase 2 clinical trials in multiple cancer types to date have shown that Pexa-Vec, delivered either directly into tumors or intravenously, induces tumor shrinkage and/or necrosis and is well-tolerated (over 250 patients treated to date). Objective tumor responses have been demonstrated in a variety of cancers including liver, colon, kidney, lung cancer and melanoma. Pexa-Vec has had a predictable and manageable safety profile to date which includes flu-like symptoms that typically resolve in 24 hours.

Pexa-Vec is the lead product candidate from Jennerex' SOLVE™ platform, a groundbreaking approach offering new therapeutic options for patients with life-threatening cancers that can be injected directly into tumor tissue or administered systemically by infusion.

About Jennerex

Jennerex Biotherapeutics, Inc. is a clinical-stage biotechnology company focused on the development and commercialization of first-in-class, breakthrough targeted oncolytic immunotherapy products for solid tumors. The Company is focused on two main programs, lead product candidate, Pexa-Vec (JX-594, pexastimogene devacirepvec), which is in mid-stage clinical development for the treatment of advanced primary liver cancer and colorectal cancer and JX-929 which is under investigation for a variety of other solid tumors. Jennerex is headquartered in San Francisco and has related research and development operations in Ottawa, Canada and South Korea. For more information about Jennerex, please visit www.jennerex.com.

About Lee's Pharmaceutical Holdings Limited

Lee's Pharmaceutical Holdings Limited is a research-based biopharmaceutical company listed in Hong Kong with over 19 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 www.leespharm.com.

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 materialise or turns out to be incorrect.

ⁱ <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: <http://globocan.iarc.fr>, accessed on day/month/year.