Press Release

PharmaEngine Announces Initiation of Global Pivotal Trial of PEP503 (NBTXR3) in Soft Tissue Sarcoma in Asia Pacific Region

Taipei, Taiwan, May 31, 2016 – PharmaEngine Inc. (TWO: 4162) announced today that the first patient has been dosed in a global pivotal phase II/III trial of PEP503 (NBTXR3) in soft tissue sarcoma (STS) at Perpetual Succour Hospital, Cebu, Philippines.

This multi-national, randomized, open-label, two-arm pivotal phase II/III trial, referred to as Study 301 (Act.in.sarc study), is being conducted in partnership with PharmaEngine's partner, Nanobiotix S.A. (Euronext: NANO). PharmaEngine is the co-sponsor of this Study 301 in the Asia-Pacific Region. The primary objective of Study 301 is to enhance the pathological complete response rate (pCR) by dosing PEP503 through intra-tumor injection and then activated by external beam radiation therapy (EBRT). The efficacy of PEP503 combined with radiotherapy in Study 301 will be compared with that of radiotherapy alone.

The total patient enrollment of Study 301 is around 180 patients to be recruited in Europe and South Africa by Nanobiotix and in the Asia-Pacific region (Australia, Hong Kong, and Philippines) by PharmaEngine. The first patient in this global study was enrolled and dosed in Europe in the first quarter of 2015. The patient enrollment is actively ongoing now. The Global Principal Investigator is Prof. Sylvia Bonvalot, MD, PhD (Institut Curie, Paris, France). An interim analysis will be performed once two-thirds of patients have been recruited to ensure the safety of all patients enrolled in the study, the quality of the data collected and the continued scientific validity of the study design.. For detailed information, please visit www.clinicaltrials.gov. (Identifier: NCT02379845).

"We are pleased to have the first patient enrolled in the Asia-Pacific region as part of the global pivotal STS study," said C. Grace Yeh, Ph.D., President and Chief Executive Officer of PharmaEngine, "The promising results from Nanobiotix's phase I/II clinical trials in STS and head & neck cancer encouraged us to accelerate the global clinical development and speed up the regulatory registration process as a medical device."

The first patient receiving the first dose of the pivotal study is one of the development

milestones in the Licensing and Collaboration Agreement between PharmaEngine and Nanobiotix. PharmaEngine will pay a milestone payment of US$1 million to Nanobiotix.

About PEP503 (NBTXR3)

PEP503, the lead project of the NanoXray pipeline of Nanobiotix, is a nanoparticle formulation of hafnium oxide crystals for the local treatment of tumors to enhance the efficacy of radiotherapy. In August 2012, PharmaEngine licensed the development and commercialization rights of NBTXR3 in the Asia-Pacific region from Nanobiotix. Nanobiotix reported the positive results of the pilot study for NBTXR3 at the 2014 ASCO Annual Meeting in Chicago, and the preliminary safety results in the head and neck cancer study which showed that the patients tolerated NBTXR3 well, with promising signs of anti-tumor activity in 2015. In addition, Nanobiotix started a Phase I/II clinical trial in liver cancers (liver metastasis and hepatocellular carcinoma) in Europe and received the approval of Investigational New Drug (IND) application of phase I/II study in prostate cancer from the US FDA. PharmaEngine started a phase 1b/2 study in rectal cancer in Taiwan. PEP503 has been classified as a class III medical device in many European and certain Asian countries.

About PharmaEngine, Inc. (TWO: 4162)

PharmaEngine, Inc. is a commercial stage oncology company headquartered in Taipei, Taiwan with a wholly owned subsidiary, PharmaEngine Europe Sarl in Paris, France. PharmaEngine focuses on the development of new medications for the treatment of cancer and Asian prevalent diseases. PharmaEngine has three ongoing projects: ONIVYDE® (Irinotecan Liposome Injection) has received regulatory approvals by the TFDA and the US FDA for the treatment of metastatic pancreatic cancer patients who progressed on gemcitabine; PEP503 (NBTXR3) in a global pivotal trial of soft tissue sarcoma and a phase 1b/2 study of rectal cancer; and PEP06 in drug discovery. For further information, please visit PharmaEngine's website at http://www.pharmaengine.com.

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