Press Release

PharmaEngine Announces Initiation of Phase 1b/2 Trial of PEP503 (NBTXR3) in Head and Neck Cancer

Taipei, Taiwan, Oct. 19, 2016 – PharmaEngine Inc. (TWO: 4162) announced today that the first patient has been dosed in a phase 1b/2 trial of PEP503 (NBTXR3) of head and neck squamous cell carcinoma (HNSCC) at Keelung Chang Gung Memorial Hospital (Lovers Lake Branch) in Keelung, Taiwan. The Principal Investigator is Prof. Cheng-Hsu Wang, M.D.

This prospective, open-label, single arm, non-randomized study (PEP503-HN-1002) of PEP503 in patients with HNSCC is being conducted in Taiwan by PharmaEngine. The primary objectives of this study are to determine the optimal dose, safety and preliminary efficacy of PEP503 through intra-tumor injection in combination with the standard treatment of concurrent chemoradiotherapy (CCRT) in SCC of oral cavity. A maximum of 42 patients may be enrolled in the phase 1b/2 study. For detailed information, please visit www.clinicaltrials.gov. (Identifier: NCT02901483).

Our partner, Nanobiotix is conducting a head and neck cancer study (NBTXR3 Study-102) of NBTXR3 (PEP503) in combination with radiation in elderly patients with SCC of oral cavity and oropharynx, who are not suitable for chemotherapy plus radiotherapy. These two studies will then identify the optimal doses for patients who can or cannot receive chemotherapy with radiotherapy plus NBTXR3 (PEP503).

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 encouraging safety and efficacy results of NBTXR3 in a pilot phase 1 clinical study of soft tissue sarcoma at the 2014 ASCO Annual Meeting in Chicago. Later in 2015 and 2016, the preliminary safety results and promising signs of tumor volume response of adding NBTXR3 to standard regimen of radiotherapy were reported in the phase 1/2 head and neck cancer study (NBTXR3 Study-102). In addition, Nanobiotix started a phase 1/2 clinical trial in liver cancers (liver metastasis and hepatocellular carcinoma) in Europe, and received the approval of an Investigational New Drug (IND) application of phase 1/2 study in prostate cancer

from the US FDA. PharmaEngine started a phase 1b/2 study in rectal cancer in Taiwan in 2015. 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 Taiwan FDA, the US FDA, and the European Medicines Agency (EMA) for the treatment of metastatic pancreatic cancer patients who progressed on gemcitabine based therapy; PEP503 (NBTXR3) in a global pivotal trial of soft tissue sarcoma, a phase 1b/2 study of rectal cancer and a phase 1b/2 study of head and neck cancer; and PEP06 in lead optimization. For further information, please visit PharmaEngine's website at http://www.pharmaengine.com.

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