Press Release

PharmaEngine announce its partner, Nanobiotix, received CE Mark approval of PEP503 (NBTXR3, Hensify®) for the treatment of locally advanced soft tissue sarcoma

Taipei, Taiwan, April 7, 2019 – PharmaEngine's (TWO: 4162), announced that its partner, Nanobiotix (Euronext: NANO), received CE Mark approval of PEP503 (NBTXR3), a radioenhancer, for the treatment of locally advanced soft tissue sarcoma. The CE Mark approval enables commercialization of PEP503 (NBTXR3), under the brand name of Hensify®, in 27 European Union countries. The approval is based on data from the phase II/III pivotal Study 301 (act.in.sarc study). The trial has been conducted and co-sponsored with PharmaEngine, Inc. (Taipei, Taiwan), Nanobiotix's Asian partner.

For further information regarding Nanobiotix's press release, please refer to the following link：
http://www.nanobiotix.com/download/news_en/2019/PR_Nanobiotix_marquage_CE_04042019_VF.pdf

About PEP503 (NBTXR3, Hensify®)

PEP503, the lead project of the NanoXray pipeline of Nanobiotix, is a nanoparticle formulation of hafnium oxide crystals. It is a first-in-class product designed to destroy, when activated by radiotherapy, tumors through physical cell death and metastasis via immunogenic cell death leading to specific activation of the immune system. In August 2012, PharmaEngine licensed the development and commercialization rights of NBTXR3 in the Asia-Pacific region from Nanobiotix. In addition to STS, Nanobiotix and PharmaEngine are performing clinical trials in head & neck cancers, liver cancers (liver metastasis and hepatocellular carcinoma), rectal cancer, prostate cancer, as well as in combination with anti-PD1 antibodies in head & neck cancers and non-small cell lung cancer. PEP503 has been classified as a class III medical device in many European and certain Asian countries.

About Soft Tissue Sarcoma (STS)

STS are rare malignant tumors that arise from extraskeletal connective tissues, accounting for 0.7% of all cancers. They can occur anywhere in the body, but most originate in an extremity and the trunk (78%). The conventional treatment for STS is

wide margin surgery whenever possible with the addition of radiotherapy. In locally advanced STS, however, clear margins are not often achievable, which could lead to higher local failure rates, and negatively affect overall survival. Scientific reports have demonstrated how preoperative radiotherapy can offset the negative prognostic impact of marginal resection on local outcome and survival for patients with STS, extending the limit of limb and function preservation.

Although improvements in surgical techniques and preoperative radiotherapy have been made, local tumor recurrence and distant metastases have been frequently noted to develop. PEP503 (NBTXR3), a radio-enhancer designed to maximize x-ray absorption within the tumor, aims to improve the efficacy of radiotherapy and increase the feasibility of surgical tumor removal.

About Study 301 (act.in.sarc study)

This prospectively randomized, multi-national, open-label and active controlled two-arm (1:1 ratio) pivotal phase II/III trial, referred to as Study 301 (act.in.sarc study) has been conducted in partnership with Nanobiotix. PharmaEngine is the co-sponsor of this study in Asia-Pacific Region. The primary objective of Study 301 is to enhance pathological Complete Response Rate (pCRR) by dosing PEP503 through intra-tumor injection and then activated by standard dose (25 x 2 Gy) of external beam radiation therapy (EBRT). The pCRR on the combination arm was 16.1% as compared to 7.9% for the control arm of radiotherapy alone ($p = 0.0448$). The secondary endpoints are the objective response rate (ORR) by imaging (MRI); the tumor volume changes; the resection margins (R0 rate) and the limb amputation rate, as well as the evaluation of the safety profile in term of clinical and laboratory adverse events. PEP503 activated by radiation demonstrated a significant increase of R0 resection rate as compared to radiation alone ($p = 0.042$). PEP503 demonstrated a good local tolerance among this patient population. The findings showed a very similar radiation-related safety profile in both arms.

The Study 301 recruited a total of 180 patients in Europe (36 sites in 10 countries) by Nanobiotix, and in Asia-Pacific region (7 sites in Australia, Hong Kong, and Philippines) by PharmaEngine. The Global Principal Investigator is Dr. Sylvie Bonvalot, MD, PhD (Head of Sarcoma and Complex Tumor Surgery Unit, Institut Curie, Paris, France). The primary endpoint of pCRR was defined as the rate of patients showing less than 5% of

residual viable cancer cells in the tumor post treatment. A centralized evaluation of the pathological response was performed. For additional information, please visit www.clinicaltrials.gov. (Identifier: NCT02379845).

About PharmaEngine (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 marketing authorizations in Taiwan, US, Europe and other countries for the treatment of metastatic pancreatic cancer patients who progressed on gemcitabine; PEP503 (NBTXR3, Hensify®) in a positive global pivotal trial of soft tissue sarcoma, and in other cancers; and PEP06 in preclinical development. For further information, please visit PharmaEngine's website at http://www.pharmaengine.com.

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