Press Release

PharmaEngine Announces Onivyde® Receives European Marketing Authorization for the Treatment of Metastatic Adenocarcinoma of the Pancreas Following Gemcitabine Based Therapy

PharmaEngine Eligible to Receive US$25 Million of Milestone Payment

Taipei, Taiwan, October 18, 2016 -- PharmaEngine, Inc. (TWO: 4162) announced that the European Commission (EC) has granted Shire plc (PharmaEngine's sublicensee, LSE: SHP, NASDAQ: SHPG) a marketing authorization (MA) for ONIVYDE® (pegylated liposomal irinotecan hydrochloride trihydrate, nal-IRI) in combination with 5-fluorouracil (5-FU) and leucovorin (LV) for the treatment of metastatic adenocarcinoma of the pancreas in patients who have progressed following gemcitabine based therapy.

With this approval, Shire (formerly Baxalta) is authorized to market ONIVYDE in the 28 Member States of the European Union (EU), as well as in Iceland, Liechtenstein and Norway. The approved dose of ONIVYDE in combination with 5-FU/LV is 80 mg/m^2 irinotecan hydrochloride trihydrate every two weeks, which is also the FDA-approved dose regimen for pancreatic cancer in Taiwan.

The approval follows on the positive opinions from the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Orphan Medicinal Products (COMP) and is based on data from the phase 3 NAPOLI-1 study. The NAPOLI-1 study demonstrated that ONIVYDE in combination with 5-FU/LV extended overall survival and progression-free survival and increased tumor response rate, without compromising quality of life as compared to 5-FU/LV alone in metastatic pancreatic cancer patients who have progressed after gemcitabine-based therapy. It is the first and only therapy approved by the US FDA and the European Medicines Agency (EMA) in this setting. In September 2015, the European Society of Medical Oncology (ESMO) stated that the use of MM-398 (ONIVYDE) when available in all countries, may be the best option for patients following gemcitabine-based therapy.

"We sincerely appreciate the joint team efforts from Merrimack (NASDAQ: MACK) and their licensee, Shire, for having successfully obtained the European marketing approval," said C. Grace Yeh, Ph.D., President and CEO of PharmaEngine. "We are excited that ONIVYDE will now be available to treat the post-gemcitabine pancreatic

cancer patients in the EU which is one of the major markets that we licensed to Merrimack."

About Pancreatic Cancer

According to GLOBOCAN, pancreatic cancer prognosis is typically poor, with an estimated 337,900 new cases and 330,400 deaths each year. However, the early stages of pancreatic cancer do not usually produce symptoms, so the disease is generally advanced when it is diagnosed. Metastatic pancreatic cancer is a highly fatal disease. Therapies are designed to control disease and extend survival. Gemcitabine, both as monotherapy as well as in combination, is commonly used in the first-line treatment of locally advanced and/or metastatic pancreatic adenocarcinoma, as well as in the adjuvant (treatment after surgery) and neo-adjuvant (treatment before surgery) settings.

About ONIVYDE® (irinotecan liposome injection, pegylated liposomal irinotecan hydrochloride trihydrate, nal-IRI)

ONIVYDE®, also known as MM-398 or PEP02, is a novel encapsulation of irinotecan in a liposomal formulation. In May 2011, PharmaEngine licensed its Asian and European rights except Taiwan to Merrimack. Following the announcement of positive top line phase 3 data in May 2014, Merrimack licensed the rights to ONIVYDE outside of the US and Taiwan to Baxalta Incorporated (now Shire) in September 2014. ONIVYDE has received regulatory approvals from the Taiwan FDA (TFDA) and the US FDA in October 2015, and the Marketing Authorization by the EC in October 2016. PharmaEngine received the Product License from the TFDA in March 2016. ONIVYDE has orphan drug designations in the US, EU and elsewhere.

About PharmaEngine (TWO: 4162)

PharmaEngine, Inc. is a publicly traded 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® has received regulatory approvals by the TFDA, the US FDA and the EMA; PEP503 (NBTXR3) is in a global pivotal trial of soft tissue sarcoma, a phase 1b/2 study of rectal cancer, and a phase 1/2 study of head and neck cancer in Taiwan; and PEP06 is in lead optimization. For further information, please visit PharmaEngine's website at http://www.pharmaengine.com.

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