Press Release

PharmaEngine Announces The Lancet Publication of the ONIVYDE™ Phase 3 NAPOLI-1 Study

Taipei, Taiwan, November 23, 2015 -- PharmaEngine, Inc. (TWO: 4162) announced that The Lancet has published the manuscript entitled “Nanoliposomal irinotecan with fluorouracil and leucovorin in metastatic pancreatic cancer after prior gemcitabine-based therapy (NAPOLI-1): a global, randomized, open-label phase 3 trial” online in advance of its print issue. The Lancet is one of the most prestigious and best known journals in the medical field.

The NAPOLI-1 study results showed that ONIVYDE™ (also known as PEP02, MM-398, nal-IRI) in combination with fluorouracil (5-FU) and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy demonstrated a clinically and statistically significant improvement in overall survival. ONIVYDE was granted regulatory approvals by the Taiwan FDA and the U.S. FDA on October 22, 2015.

“NAPOLI-1 study is the first phase 3 registration trial successfully demonstrating survival benefits of the ONIVYDE/5-FU/LV combination in the metastatic pancreatic cancer patients in the post-gemcitabine setting. I am delighted and privileged to have participated in the entire clinical development of ONIVYDE. I hope that ONIVYDE can offer clinically meaningful benefits to patients facing this devastating disease in the near future.” said Prof. Li-Tzong Chen, Director of National Institute of Cancer Research, National Health Research Institutes, Tainan, Taiwan.

About NAPOLI-1

NAPOLI-1 was conducted in patients with metastatic pancreatic cancer who previously received gemcitabine-based therapy. A total of 417 patients were recruited at 76 sites in 14 countries; 95 patients (22.8%) were from Taiwan which ranked the top enrollment rate. The study results of NAPOLI-1 showed ONIVYDE in combination with 5-FU/LV achieved the primary and secondary endpoints by demonstrating a statistically significant improvement in overall survival, progression free survival and overall response rate compared to the control group of patients who received 5-FU/LV. The ONIVYDE monotherapy arm in this study did not achieve the primary endpoint. The most common adverse reactions (≥ 20%) with ONIVYDE were

diarrhea, fatigue/asthenia, vomiting, nausea, decreased appetite, stomatitis and pyrexia and the most common severe laboratory abnormalities (≥10% Grade 3 or 4) were lymphopenia and neutropenia. This was the first global Phase 3 study in a post-gemcitabine setting to demonstrate a survival benefit in this aggressive disease.

About Pancreatic Cancer

According to the most recent information from World Health Organization (WHO), 330,000 people die of pancreatic cancer per year and pancreatic cancer is the seventh-leading cause of cancer-related death in the world. Metastatic pancreatic cancer is almost uniformly fatal, with an overall survival rate of approximately 6 percent at 5 years worldwide. Currently, patients with metastatic pancreatic cancer who progress after gemcitabine treatment or FOLFIRINOX combination therapy have no set standard of care.

About ONIVYDE (MM-398, PEP02, nal-IRI)

PharmaEngine licensed the Asian (2003) and European (2005) development, manufacturing and commercialization rights for ONIVYDE from Hermes BioSciences, Inc., South San Francisco, CA. Hermes was acquired by Merrimack Pharmaceuticals, Inc., Cambridge, MA in 2009. After completed preclinical, Phase 1 and 2 clinical studies, PharmaEngine licensed its Asian and European rights, except Taiwan, back to Merrimack in 2011. From 2012 to 2014, Merrimack sponsored the global Phase 3 study in metastatic pancreatic cancer patients who progressed after receiving a gemcitabine-containing regimen. In September 2014, Merrimack licensed ONIVYDE outside of the U.S. and Taiwan to Baxalta Incorporated (NYSE: BXLT), formerly Baxter International's BioScience business. ONIVYDE was granted regulatory approvals by the Taiwan FDA and the U.S. FDA on Oct. 22, 2015. ONIVYDE's marketing authorization application was accepted and under the regulatory review of European Medicines Agency (EMA) since June 2015. Baxalta is planning for submissions of ONIVYDE to other countries. ONIVYDE is designated as orphan drug in the US, EU and elsewhere.

About PharmaEngine (TWO: 4162)

PharmaEngine, Inc. is a biopharmaceutical company headquartered in Taipei, Taiwan, with a wholly owned subsidiary of 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: PEP02 (MM-398, ONIVYDE) is approved by the TFDA and U.S. FDA and under the NDA review by the EMA; PEP503 (NBTXR3) in a global pivotal trial of soft tissue sarcoma; and PEP06 in lead optimization. For further information, please visit PharmaEngine's website at http://www.pharmaengine.com.

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