Press Release

PharmaEngine Announces Taiwan FDA Granting the Product License of ONIVYDE™ (Irinotecan Liposome Injection) for the Treatment of Metastatic Pancreatic Cancer

Taipei, Taiwan, March 5, 2016 -- PharmaEngine, Inc. (TWO: 4162) announced that TFDA (Taiwan Food and Drug Administration) approved the product license of ONIVYDE™ (irinotecan liposome injection, nal-IRI). ONIVYDE is indicated, in combination with fluorouracil (5-FU) and leucovorin (LV), for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

There are two steps for the marketing approval of new drugs in Taiwan. The first step is to assess whether the chemistry, manufacturing and controls, preclinical and clinical data regarding the quality, safety and efficacy are sufficient to issue the regulatory approval letter; and the second step is to assess whether the product labeling and package insert are supported by the new drug application dossiers. Both steps are essential for product sales in the Taiwan market. ONIVYDE has been granted the TFDA regulatory approval letter on October 22, 2015. The approval of the commercial packaging materials and the GMP approval letters for two US manufacturing sites have been issued to allow the TFDA granting the product license of ONIVYDE. PharmaEngine's sales and marketing team is building the pharmacovigilance communication system to ensure the patient safety after product launch. We expect ONIVYDE to be available in Taiwan during the second quarter of this year.

"We are very grateful that the TFDA accelerated the approval of the product license in such an expedited manner," said C. Grace Yeh, Ph.D., President and CEO of PharmaEngine. "In addition, we highly appreciate our license partner, Merrimack Pharmaceuticals, Inc. for their total support during the review period. Today marks a new era that transforms PharmaEngine from a research and development company to a commercial pharma company. "

About Pancreatic Cancer

According to the statistical data in 2013 from the Ministry of Health and Welfare (MOHW), pancreatic cancer is the eighth leading cause of cancer deaths in Taiwan and about 1,700 people die of pancreatic cancer every year. Metastatic pancreatic

cancer is a highly lethal disease. Therapies are designed to control disease and extend survival. Gemcitabine is one of the drugs commonly used for the first-line therapy of pancreatic cancer. Currently, ONIVYDE is the only approved drug for the patients with metastatic pancreatic cancer who progressed following gemcitabine treatment.

About ONIVYDE™ (irinotecan liposome injection, nal-IRI)

ONIVYDE, also known as MM-398 or PEP02, is a novel encapsulation of irinotecan in a liposomal formulation. The active metabolite of irinotecan is SN-38, which functions by inhibiting topoisomerase I (an essential enzyme involved in DNA transcription and replication) and promoting cell death. PharmaEngine licensed the Asian and European development, manufacturing and commercialization rights of ONIVYDE from Hermes Biosciences, Inc., South San Francisco, CA. Hermes was acquired by Merrimack Pharmaceuticals, Inc., Cambridge, MA in 2009. After completing preclinical, phase 1 and 2 clinical studies, PharmaEngine licensed its Asian and European rights except Taiwan, back to Merrimack in 2011.

During 2011 and 2014, Merrimack sponsored the global phase 3 NAPOLI-1 study in metastatic pancreatic cancer patients. 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 has received regulatory approvals by the TFDA and the US FDA and is under the Marketing Authorization Application (MAA) review by the European Medicines Agency (EMA). ONIVYDE has orphan drug designation 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, 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 and the US FDA and is under the MAA review by the EMA; PEP503 (NBTXR3) is in a global pivotal trial of soft tissue sarcoma and a phase 1b/2 study of rectal 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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Contact

Chihsing Chang, Vice President, Finance and Administration
Telephone No.: (+886)-2-2515-8228, ext. 700
Email: chihsing.chang@pharmaengine.com