Press Release

PharmaEngine Announces Korean Ministry of Food and Drug Safety Accepted the NDA Filing of ONIVYDE® for the Treatment of Metastatic Pancreatic Cancer

- This milestone triggers US$10 million payment to PharmaEngine -

Taipei, Taiwan, May 11, 2016 -- PharmaEngine, Inc. (TWO: 4162) announced that Korean Ministry of Food and Drug Safety (MFDS, previously called Korean Food and Drug Administration) accepted the submission of a new drug application (NDA) of ONIVYDE® (irinotecan liposome injection, nal-IRI). In addition, the MFDS issued a notice letter regarding a positive opinion for the orphan drug designation of ONIVYDE in the Republic of Korea.

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.

In accordance with the License and Collaboration Agreement executed between PharmaEngine and Merrimack in May 2011, this regulatory achievement triggers US$10 million of milestone payment to PharmaEngine.

“We are very thankful to the regulatory teams of Merrimack and their licensee, Baxalta for having prepared and submitted the Korean NDA dossier which was accepted by the MFDS,” said C. Grace Yeh, Ph.D., President and CEO of PharmaEngine. “We are thrilled that ONIVYDE, once it is approved, will be available to treat the post-gemcitabine pancreatic cancer patients in the Republic of Korea which is one of the major Asian markets.”

About Pancreatic Cancer in Korea

According to the statistical data in 2014 from the World Health Organization (WHO), pancreatic cancer is the fifth leading cause of cancer deaths in the Republic of Korea and about 5,090 people die of pancreatic cancer every year. Metastatic pancreatic cancer is a highly lethal disease. Therapies are designed to control disease and extend survival.

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. 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 (NYSE: BXLT), formerly Baxter International's BioScience business in September 2014. ONIVYDE has received regulatory approvals from the Taiwan FDA and the US FDA in October 2015, and is under the Marketing Authorization Application (MAA) review by the European Medicines Agency (EMA). ONIVYDE has orphan drug designations 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; 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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