Press Release

MM-398 Receiving the Priority Review Designation by US FDA for New Drug Application and the Acceptance of Market Authorization Application by EMA in Post-Gemcitabine Metastatic Pancreatic Cancer

Taipei, Taiwan, June 25, 2015 -- PharmaEngine, Inc. (TWO: 4162) announced that (1) its license partner, Merrimack Pharmaceuticals, Inc. (NASDAQ: MACK), has received the notification from the US Food and Drug Administration (FDA) for the acceptance and the grant of the priority review designation for their New Drug Application (NDA); and (2) its sublicense partner, Baxalta Incorporated, a wholly owned subsidiary of Baxter International Inc. (NYSE: BAX) has received the acceptance of Market Authorization Application (MAA) from the European Medicines Agency (EMA), of MM-398 (irinotecan liposome injection, also known as "nal-IRI,") in the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy.

A priority review designation is granted to medicines that the US FDA determines, have the potential to provide significant improvements in the safety or effectiveness. The goal is for the FDA to take action on the marketing application within 6 months of receipt (compared with 10 months under standard review) of the NDA submission. .

"We are very excited to know that the two major regulatory agencies, the US FDA and the EMA, have accepted the NDA and MAA applications in their respective jurisdictions for MM-398," said C. Grace Yeh, Ph.D., President and CEO of PharmaEngine. "We believe that MM-398 will provide an option to the limited armamentarium for the treatment of the metastatic pancreatic cancer in the foreseeable future."

In addition, as a result of the MAA acceptance, PharmaEngine is entitled to receive a total of US$11 million from Merrimack as the milestone payment and sublicense revenue under the License and Collaboration Agreement between PharmaEngine and Merrimack.

About MM-398 (PEP02)

MM-398 (PEP02, irinotecan liposome injection), also known as "nal-IRI," is a novel, stable nanotherapeutic encapsulation of the marketed chemotherapy drug irinotecan.

In May 2011, PharmaEngine and Merrimack executed an exclusive license agreement. Under the terms of the agreement, PharmaEngine granted back Merrimack the rights to develop, manufacture, and commercialize PEP02 (designated as MM-398 by Merrimack) in Asia and Europe, and retained the same rights in Taiwan. In September 2014, Merrimack licensed the rights to MM-398 outside of the US and Taiwan to Baxter International's BioScience business.

In 2011, MM-398 received orphan drug designation from both the US FDA and the EMA for the treatment of pancreatic cancer. In April and May 2015, all three partners submitted the NDA, MAA, and NDA to the US FDA, the EMA, and the Taiwan FDA, respectively. In addition, MM-398 received Fast Track designation and Priority Review designation from the US FDA in November 2014 and June 2015, respectively.

About PharmaEngine, Inc. (TWO: 4162)

PharmaEngine is a biopharmaceutical company established in Taipei, Taiwan. 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) in NDA stage; PEP503 (NBTXR3) in a global pivotal trial of soft tissue sarcoma; and PEP06 in drug discovery. For further information, please visit PharmaEngine's website at http://www.pharmaengine.com.

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