Press Release

PharmaEngine Announces ONIVYDE® Regimen Receives CHMP Positive Opinion for the Treatment of Metastatic Pancreatic Cancer

Taipei, Taiwan, July 25, 2016 -- PharmaEngine, Inc. (TWO: 4162) announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the granting of a marketing authorization of ONIVYDE® (irinotecan liposome injection, nal-IRI) in combination with 5-fluorouracil (5-FU) and leucovorin (LV) for the treatment of metastatic adenocarcinoma of the pancreas in adult patients who have progressed following gemcitabine based therapy. The CHMP positive opinion for ONIVYDE will now be reviewed by the European Commission for marketing authorization in the European Union (EU).

Based on this recommendation, a final decision regarding the marketing approval of ONIVYDE is expected from the European Commission in 2016. The CHMP recommended approval of ONIVYDE in combination with 5-FU/LV at a dose of 70 mg/m^2 irinotecan free base (equivalent to 80 mg/m^2 irinotecan hydrochloride salt), every two weeks, is also the FDA-approved dose regimen for pancreatic cancer in the United States.

Data supporting the CHMP positive opinion were based on findings from the phase 3 NAPOLI-1 study. ONIVYDE in combination with 5-FU/LV extended overall survival and progression-free survival, increased tumor response rate, without compromising the quality of life as compared to 5-FU/LV in metastatic pancreatic cancer patients who have progressed after gemcitabine-based therapy. It is the first and only US FDA-approved therapy in this setting. The ONIVYDE combination is also designated as a category 1 treatment option in the 2016 National Comprehensive Cancer Network (NCCN) guidelines for pancreatic adenocarcinoma in the United States.

“We are thankful to the joint team efforts from Merrimack and their licensee, Shire (formerly Baxalta), for having prepared and submitted the Marketing Authorization Application (MAA) to the EMA in May 2015, and glad to have participated during the review process,” 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 European Union which is one of the major markets that we licensed to Merrimack.”

About Pancreatic Cancer

According to GLOBOCAN, Pancreatic cancer is the twelfth most common cancer in the world, with 338,000 new cases diagnosed in 2012. 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 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 (now Shire) in September 2014. ONIVYDE has received regulatory approvals from the Taiwan FDA (TFDA) 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 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 and the US FDA, as well as the positive opinion from the CHMP of 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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