Press Release

PharmaEngine Announces Singapore Health Sciences Authority Approved ONIVYDE® for the Treatment of Metastatic Pancreatic Cancer

Taipei, Taiwan, January 16, 2018 -- PharmaEngine, Inc. (TWO: 4162) announced that Health Sciences Authority (HSA) of Singapore has approved ONIVYDE® (liposome irinotecan) 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. This is the second approval for ONIVYDE granted in one of the Asian major countries, following the marketing authorization approved by the Korea Ministry of Food and Drug Safety in August 2017. As the new drug approval granted from Singapore is considered an important indicator for the regulatory authorities in the other nine member states of the Association of Southeast Asian Nations (ASEAN) when reviewing NDA (New Drug Application), it is expected that the market entry of ONIVYDE into the Southeast Asia region could be accelerated.

The approval from Singapore is based on data from the phase 3 NAPOLI-1 study. The NAPOLI-1 study demonstrated that ONIVYDE in combination with 5-FU/LV extended overall survival, progression-free survival and increased tumor response rate, without compromising quality of life as compared to 5-FU/LV alone in metastatic pancreatic cancer patients who have progressed after gemcitabine-based therapy.

“We sincerely appreciate the efforts made by Shire’s regulatory team in close communication and cooperation with HSA for obtaining the marketing approval in Singapore. As a result, the commercialization of ONIVYDE could be expanded into the ASEAN countries sooner,” said C. Grace Yeh, Ph.D., President and CEO of PharmaEngine. “Through joint team efforts with Ipsen and Shire in life cycle management and their wide distribution networks, we believe that positive impacts can be made and the clinical benefits of ONIVYDE will be brought to the pancreatic cancer patients globally.“

About Pancreatic Cancer in Southeast Asia

According to the statistical data from the World Health Organization, there were 11,858 people dying of pancreatic cancer in Southeast Asia in 2012. So far, metastatic pancreatic cancer is still a highly lethal disease. Therapies are designed to control disease and extend survival.

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

ONIVYDE, also known as nal-IRI, 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 (NASDAQ: MACK). In September 2014, Merrimack licensed the rights to ONIVYDE outside of the US and Taiwan to Baxalta Incorporated (NYSE: BXLT), formerly Baxter International's BioScience business, subsequently Baxalta was acquired by Shire (LSE: SHP, NASDAQ: SHPG) in July 2016. Then in April 2017, Ipsen (Euronext: IPN; ADR: IPSEY) acquired the exclusive US commercial rights of ONIVYDE, as well as took over the licensing agreements with Shire and with PharmaEngine from Merrimack. So far, ONIVYDE has been approved in Taiwan, US, EU, Australia, Canada, South Korea, and now Singapore, it also received orphan drug designations in the US, EU, and other countries.

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 in 37 countries; PEP503 (NBTXR3) is in a global pivotal trial of soft tissue sarcoma, and patient recruitment has been completed; and PEP06 is in preclinical development. For further information, please visit PharmaEngine's website at http://www.pharmaengine.com.

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