



Press Release

## **PharmaEngine Announces ONIVYDE<sup>®</sup> Obtained Reimbursement from Taiwan's National Health Insurance Administration**

*- Reimbursed price is NT\$26,400 per vial -*

Taipei, Taiwan, July 11, 2018 -- PharmaEngine, Inc. (TWO: 4162) announced that Taiwan's National Health Insurance Administration (NHIA) has approved the reimbursement for ONIVYDE<sup>®</sup> (liposome irinotecan) starting from August 1, 2018, with the reimbursement price set at NT\$26,400 per vial. NHIA has approved ONIVYDE to be used in combination with fluorouracil (5-FU) and leucovorin (LV) for patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. This is the first new cancer drug developed from Taiwan which received reimbursement from NHIA. With the positive decision for ONIVYDE, patients are provided with access to a drug that is very likely to change the way metastatic pancreatic cancer is treated in Taiwan.

The recommendation was based on data from the global phase 3 NAPOLI-1 study, demonstrating 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. ONIVYDE has been recommended by ESMO (European Society of Medical Oncology, 2015) and NCCN (The National Comprehensive Cancer Network, 2016) Clinical Practice Guidelines to be the standard of care in this patient population.

"We would like to thank the diligent and expedient process by the reviewers at NHIA since we submitted the application last July, and we are delighted that NHIA will now provide ONIVYDE to more patients battling metastatic pancreatic cancer in Taiwan," said C. Grace Yeh, Ph.D., President and CEO of PharmaEngine. "This reimbursement approval for the drug developed from Taiwan is also a great encouragement for the domestic biopharmaceutical companies dedicated to new drug development. We will continue to develop new treatment options to alleviate the suffering and prolong the lives of cancer patients worldwide."

### **About Pancreatic Cancer in Taiwan**

According to the statistical data in Taiwan from Health Promotion Administration, Ministry of Health and Welfare, in 2015, 2,237 people were newly diagnosed with



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pancreatic cancer, and 1,948 people died from the disease, the eighth leading cause of cancer death in Taiwan. So far, metastatic pancreatic cancer is still a highly devastating disease. Current therapies are designed to control disease and extend survival.

### **About ONIVYDE<sup>®</sup> (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: BXL), 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 Singapore. It also received orphan drug designations in the US, EU, and other countries.

### **About PharmaEngine (TWO: 4162)**

PharmaEngine, Inc. is a 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 (Irinotecan Liposome Injection) has received marketing authorizations in Taiwan, US, Europe and other countries for the treatment of metastatic pancreatic cancer patients who progressed on gemcitabine; PEP503 (NBTXR3) in a positive global pivotal trial of soft tissue sarcoma, and in other cancers; and PEP06 in preclinical development. For further information, please visit PharmaEngine's website at <http://www.pharmaengine.com>.

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