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Singapore: Taiwan's PharmaEngine has recieved Taiwan Food and Drug Administration (TFDA) approval for ONIVYDE (irinotecan liposome injection) 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.

"We are very grateful that the TFDA granted the regulatory approval in such a rapid pace, especially the accelerated efforts made by the Center of Drug Evaluation (CDE) and the TFDA," said Dr C Grace Yeh, president and CEO, PharmaEngine. "We are highly appreciative to our license partner, Merrimack Pharmaceuticals, for their valuable collaboration, as well as their timely and full support during the review period. Also, we sincerely thank all the patients, the investigators and their caregivers for their participation and significant contribution to advance the management of pancreatic cancer patients. Lastly, PharmaEngine is proud of this remarkable achievement in our company's history, and we are indebted to many people who encouraged us to persevere for more than a decade in developing ONIVYDE."

ONIVYDE (formerly known as MM-398, PEP02, or nal-IRI) is a proprietary liposome encapsulation of irinotecan, a topoisomerase 1 inhibitor. The new drug application (NDA) to the TFDA was based on the NDA data package submitted by Merrimack to the US FDA.

Merrimack submitted an NDA to the US FDA in April 2015 and was granted priority review in June with a Prescription Drug User Fee Act (PDUFA) date of October 24, 2015. The marketing authorization application (MAA) submitted to the European

Medicines Agency (EMA) by Baxalta Incorporated in May 2015, was accepted for review in June 2015, and there are plans for submissions to other countries. ONIVYDE has orphan drug designation in the US, EU and elsewhere.