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Singapore: Taiwan based PharmaEngine has recieved Taiwan Food and Drug Administration (TFDA) approval of the product license of ONIVYDE (irinotecan liposome injection, nal-IRI).

ONIVYDE is indicated, 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.

There are two steps for the marketing approval of new drugs in Taiwan. The first step is to assess whether the chemistry, manufacturing and controls, preclinical and clinical data regarding the quality, safety and efficacy are sufficient to issue the regulatory approval letter; and the second step is to assess whether the product labeling and package insert are supported by the new drug application dossiers. Both steps are essential for product sales in the Taiwan market.

"We are very grateful that the TFDA accelerated the approval of the product license in such an expedited manner," said C. Grace Yeh, president and CEO of PharmaEngine. "In addition, we highly appreciate our license partner, Merrimack Pharmaceuticals for their total support during the review period. Today marks a new era that transforms PharmaEngine from a research and development company to a commercial pharma company. "