BioSpectrum the business of Bio & Health Sciences ASIA EDITION

PharmaEngine files NDA for metastatic cancer drug

02 June 2015 | News | By BioSpectrum Bureau

PharmaEngine files NDA for metastatic cancer drug

Singapore: Taiwan's PharmaEngine has filed a New Drug Application (NDA) to the Taiwan Food and Drug Administration (TFDA) for MM-398 (irinotecan liposome injection, also known as nal-IRI) in patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy.

The filing of MM-398 to the TFDA follows the recent submissions of NDA and marketing authorization application (MAA) by its licensing partner, Merrimack Pharmaceuticals and its sublicensing partner, Baxter International's BioScience business to the US FDA and to the European Medicines Agency, respectively.

The filing of MM-398 to the TFDA was supported by the positive data from a phase 3 study (NAPOLI-1) conducted in patients with metastatic pancreatic cancer who previously received gemcitabine-based therapy. "This submission represents a significant milestone in the history of PharmaEngine. We are extremely grateful to our investigators, patients and their caregivers for their participation in making Taiwan the top recruitment region in this pivotal study. We are also thankful for the support from Merrimack in preparing our NDA," said Dr C Grace Yeh, president and CEO, PharmaEngine. "We look forward to working with our regulatory authority to offer a new treatment option to help the patients in fighting against their pancreatic cancer."