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Taiwan's PharmEngine initiates clinical trial of chemotherapy drug

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Singapore: Taiwan's PharmaEngine licensing partner, Merrimack Pharmaceuticals, and its sublicensing partner, Baxter International, has submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) for MM-398 (irinotecan liposome injection), in patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy.

"The filing of the MAA of MM-398 to the EMA is a significant step towards the regulatory approval in the European Union. We are very impressed by Baxter's expedited efforts in completing the MAA submission in such a short period of time," said Dr C Grace Yeh, president and CEO, PharmaEngine. "We are preparing the NDA filing of MM-398 (PEP02) to the Taiwan FDA, and hope to provide a new treatment option to pancreatic cancer patients soon."

MM-398, also known as "nal-IRI," is a novel, stable nanotherapeutic encapsulation of the marketed chemotherapy drug irinotecan.

In May 2011, PharmaEngine and Merrimack executed an exclusive license agreement. Under the terms of the agreement, PharmaEngine granted back Merrimack the rights to develop, manufacture, and commercialize PEP02 (designated as MM-398 by Merrimack) in Asia and Europe, and retained the same rights in Taiwan.

In September 2014, Merrimack licensed the rights to MM-398 outside of the US and Taiwan to Baxter International's biopharmaceutical business. In 2011, MM-398 received orphan drug designation from both the US FDA and EMA for the treatment of pancreatic cancer. In addition, MM-398 received Fast Track Designation for post-gemcitabine metastatic pancreatic cancer from the US FDA in November 2014, and completed the rolling submission of the NDA for US FDA in April 2015.