

# FDA Grants Orphan Drug Status to Merrimack Pharmaceuticals' MM-398, a Nanotherapeutic Encapsulation of Irinotecan, for the Treatment of Pancreatic Cancer



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**Merrimack Pharmaceuticals, Inc. →**

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CAMBRIDGE, Mass., Aug. 1, 2011 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. announced today that the U.S. Food and Drug Administration (FDA) has granted MM-398 orphan drug status for the treatment of pancreatic cancer. MM-398 is a novel, stable nanotherapeutic encapsulation of the marketed chemotherapy drug irinotecan. MM-398 is partnered with PharmaEngine, Inc. for development and commercialization in Taiwan under the designation PEP02.

(Logo: <http://photos.prnewswire.com/prnh/20100913/NE63515LOGO>)

One of the purposes of the Orphan Drug Designation program is to provide orphan status to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the United States. In the United States, the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or disorder receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full new drug application (NDA), to

market the same drug for the same orphan indication, except in very limited circumstances. Orphan drug designation in the United States also provides for a reduction in regulatory fees and additional regulatory support for research and development initiatives.

### **About PharmaEngine, Inc.**

PharmaEngine is a biopharmaceutical company established in Taipei, Taiwan in 2003. The company focuses on the development of new drugs to treat cancer and Asian prevalent diseases. For further information on PharmaEngine, please visit the Company's website at <http://www.pharmaengine.com>.

### **About Merrimack**

Merrimack is a biopharmaceutical company discovering, developing and preparing to commercialize innovative medicines paired with companion diagnostics for the treatment of serious diseases, with an initial focus on cancer. Merrimack applies Network Biology, its proprietary systems biology-based approach to biomedical research, throughout the research and development process. Merrimack currently has four targeted therapeutic oncology candidates in clinical development and a fifth expected to enter clinical development by the end of 2011.

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