

August 28, 2013

## **Merrimack Reaches Patient Enrollment Goal in the Phase 3 NAPOLI-1 Study of MM-398 in Late Stage Pancreatic Cancer**

### **A Study of MM-398 Both as Monotherapy and in Combination With 5-FU and Leucovorin in Patients With Advanced Gemcitabine-Refractory Pancreatic Cancer**

CAMBRIDGE, Mass., Aug 28, 2013 (GLOBE NEWSWIRE) -- Merrimack Pharmaceuticals, Inc. (Nasdaq:MACK) announced today that the enrollment goal has been reached in the NAPOLI-1 trial. NAPOLI-1 is a randomized Phase 3 study of MM-398, with or without 5-fluorouracil (5-FU) and leucovorin (LV), versus 5-FU and LV, in patients with metastatic pancreatic cancer previously treated with gemcitabine-based therapy.

"We are grateful to the patients and their families for volunteering for the study, and to the doctors, nurses, and medical teams for their outstanding care. We hope that MM-398 is able to make a difference to these patients and look forward to presenting the final study analysis," said Eliel Bayever, M.D., Vice President and Medical Director of MM-398. "To our knowledge this is one of the largest controlled studies ever conducted in this patient population, which has very few treatment options."

Currently, there is no approved treatment for patients with metastatic pancreatic cancer after gemcitabine has failed, nor is there a clear consensus on the standard of care in this patient group. Limited data suggest that without effective treatment, these patients are expected to live only a few months once they have progressed on first line therapy. Metastatic pancreatic cancer is almost uniformly fatal, with a 73 percent death rate within one year of diagnosis (American Cancer Society) and a 5-year overall survival rate of approximately six percent in the United States (National Cancer Institute).

NAPOLI-1 was designed to enroll approximately 405 patients at over 100 sites in North America, South America, Europe, Asia and Australia. As recently as July 2013, a data safety monitoring board reviewed the available data from NAPOLI-1 for safety and recommended that the trial continue. The Global Principal Investigator is Daniel von Hoff, M.D., F.A.C.P. of TGen, University of Arizona, Mayo Clinic and Scottsdale Healthcare.

#### **About MM-398**

MM-398 is a novel nanoliposomal encapsulation of irinotecan sucrosfate. MM-398 is designed to optimize the delivery of irinotecan by extending the duration of circulation in the body and preferentially activating the drug within the tumor to achieve higher levels of the active drug, SN-38. MM-398 has been evaluated in several clinical trials including a Phase 2 single agent study of MM-398 in metastatic pancreatic cancer, an ongoing Phase 2 study of MM-398 in combination with 5-FU and LV in patients with metastatic colorectal cancer, and a Phase 1 cross indication translational study. MM-398 is not approved for any indication by the FDA or any other regulatory agency. The salt form of the active ingredient within MM-398 liposomes was recently assigned the non-proprietary name - irinotecan sucrosfate, by the USAN (United States Adopted Name) Council.

#### **About Merrimack**

Merrimack is a biopharmaceutical company discovering, developing and preparing to commercialize innovative medicines paired with companion diagnostics for the treatment of cancer. Merrimack applies its systems biology-based approach to biomedical research throughout the research and development process. Merrimack currently has six oncology therapeutics in clinical development. Under a 2011 agreement with PharmaEngine, Inc. (Taipei, Taiwan), Merrimack consolidated the worldwide development and commercialization rights to MM-398, with the exception of commercialization rights in Taiwan, which are held by PharmaEngine, Inc.

#### **Forward-looking statements**

To the extent that statements contained in this press release are not descriptions of historical facts, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements include any statements about Merrimack's strategy, future operations, future financial position and future expectations and plans and prospects for Merrimack, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "hope" and similar expressions. In this press release, Merrimack's forward-looking statements include statements about the potential for MM-398 to provide clinical benefit. Such forward-looking statements involve substantial risks and uncertainties that could cause Merrimack's clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-

looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the initiation of future clinical trials, availability of data from ongoing clinical trials, expectations for regulatory approvals, development progress of Merrimack's companion diagnostics and other matters that could affect the availability or commercial potential of Merrimack's drug candidates or companion diagnostics. Merrimack undertakes no obligation to update or revise any forward-looking statements. Forward-looking statements should not be relied upon as representing Merrimack's views as of any date subsequent to the date hereof. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Merrimack's business in general, see the "Risk Factors" section of Merrimack's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 8, 2013 and other reports Merrimack files with the SEC.

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