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Study of Novel Nanoliposomal Irinotecan (MM-398) in Late Stage Pancreatic Cancer Published in British Journal of Cancer

Phase 2 Study Laid the Groundwork for Ongoing Phase 3 NAPOLI-1 Study In Gemcitabine-Refractory Pancreatic Cancer

CAMBRIDGE, Mass., Aug. 22, 2013 (GLOBE NEWSWIRE) -- Merrimack Pharmaceuticals, Inc. (Nasdaq:MACK) announced today that the *British Journal of Cancer* has published the paper "A Multinational Phase 2 Study of Nanoliposomal Irinotecan Sucrosofate (PEP02, MM-398) for Patients with Gemcitabine-Refractory Metastatic Pancreatic Cancer" in its latest issue (Volume 109, Issue 4). The Phase 2 study evaluated MM-398 (liposomal irinotecan sucrosulfate) monotherapy in patients with metastatic pancreatic cancer previously treated with gemcitabine-based therapy. A large, controlled Phase 3 study, NAPOLI-1 (NAnoliPOsomaL Irinotecan), evaluating this agent alone and in combination is underway in this patient population, and is expected to complete enrollment in the third quarter of 2013.

The Phase 2 single-arm study met its primary endpoint with 75% of patients surviving at least 3 months, including 25% reaching the 1-year mark. In this study, median overall survival was 5.2 months, and 50% of patients showed evidence of disease control. The most common severe adverse events included neutropenia, abdominal pain, asthenia and diarrhea.

"We are pleased that this study, which suggests promising results against a difficult-to-treat cancer, has been published in the respected peer-reviewed British Journal of Cancer," said Eliel Bayever, M.D., Vice President and Medical Director of MM-398. "This study laid the groundwork for our subsequent, ongoing phase 3 study of nanoliposomal irinotecan sucrosofate in the same patient population."

About NAPOLI-1

NAPOLI-1 is a global, randomized, open label Phase 3 trial testing MM-398 as a monotherapy and MM-398 in combination with 5-FU/LV compared with the shared control arm of 5-FU/LV. The study was designed to enroll approximately 405 patients at over 100 sites in North America, South America, Europe, Asia and Australia. The Global Principal Investigator is Daniel von Hoff, M.D., F.A.C.P. of TGen, University of Arizona, Mayo Clinic and Scottsdale Healthcare. 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 therapy, 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).

About MM-398

MM-398 is a novel nanoliposomal encapsulation of irinotecan sucrosofate. 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 cytotoxic, SN-38. MM-398 has been or is being evaluated in several clinical trials including a Phase 2 single agent study of MM-398 in metastatic pancreatic cancer, now in Phase 3, 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 sucrosofate, 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. Merrimack holds the development and commercialization rights to MM-398 worldwide, with the exception of Taiwan. Merrimack has licensed the Taiwanese commercialization rights to PharmaEngine, Inc. (Taipei), which conducted previous studies of MM-398 under the designation PEP02. This Phase 2 was supported by PharmaEngine, Inc. (Taipei, Taiwan), who provided a research grant and supplied PEP02/MM-398 to conduct the trial.

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, the timing for completion of enrollment of clinical studies, and the timing of release of study results. 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, 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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