June 27, 2012

Merrimack Announces Expansion of Phase 3 NAPOLI-1 Study of MM-398 in Late Stage Pancreatic Cancer

Expansion to Include MM-398 in Combination With 5-Fluorouracil and Leucovorin

Additional Arm Explores Broader Usage of MM-398 in a Setting Where Combination Therapy is Becoming More Common

CAMBRIDGE, Mass., June 27, 2012 (GLOBE NEWSWIRE) -- Merrimack Pharmaceuticals, Inc. (Nasdaq:MACK) announced today that it has expanded the global Phase 3 study of MM-398 versus an infusional regimen of 5-fluorouracil (5-FU) and leucovorin (folinic acid) (LV) in patients with metastatic pancreatic cancer where a gemcitabine-containing regimen has failed. The study has been expanded to include an additional arm which combines MM-398 with 5-FU and LV. The Phase 3 study, called NAPOLI-1 (NAnoliPOsomaL Irinotecan), is scheduled to begin enrollment on the amended protocol in July.

MM-398 is a novel, stable nanoliposomal encapsulation of the conventional chemotherapy irinotecan. 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.

"We believe that expanding the trial will greatly enhance the design and our long term ability to favorably impact patients with this terrible disease," said Eliel Bayever, M.D., a Vice President at Merrimack and the medical director for MM-398. "Physicians have increasingly been utilizing combination treatments for patients with second line pancreatic cancer if they feel that the patient is well enough to tolerate more aggressive treatment. We are responding to that trend with this enhanced design."

NAPOLI-1 is a global, randomized, open label Phase 3 study. The protocol amendment enlarges the study population by 135 patients, calling for a total enrollment of 405 patients equally randomized across the three arms: MM-398 as a monotherapy and MM-398 in combination with 5-FU/LV compared with the shared control arm of 5-FU/LV.

"Recruitment of the monotherapy study is on track and we are pleased with investigator enthusiasm and patient availability so far. We feel that adding the additional combination arm at this time takes advantage of the global infrastructure and momentum that we have in place while efficiently testing two MM-398 regimens within a single study to more broadly explore its use in pancreatic cancer," said Clet Niyikiza, Ph.D., Executive Vice President of Development at Merrimack.

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 is designed to enroll 405 patients at over 100 sites in North America, South America, Europe, Asia, Australia and South Africa. The Global Principal Investigator is Daniel von Hoff, M.D., F.A.C.P. of TGen, University of Arizona, Mayo Clinic and Scottsdale Healthcare. For a complete list of study sites, please visit www.clinicaltrials.gov. There is no approved treatment for patients with metastatic pancreatic cancer where a gemcitabine-containing treatment has failed, nor is there a consensus on the standard of care. 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 an overall survival rate of approximately six percent at five years in the United States .

About MM-398

MM-398 is a novel, stable nanoliposomal encapsulation of the conventional chemotherapy irinotecan. 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 tested in several clinical trials including a Phase 2 single agent study of MM-398 in metastatic pancreatic cancer and an ongoing Phase 2 study of MM-398 in combination with 5-FU and leucovorin in patients with metastatic colorectal cancer. 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. MM-398 is not approved for any indication by the FDA or any other regulatory agency.

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 five targeted therapeutic oncology candidates in clinical development.

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," and similar expressions. In this press release, Merrimack's forward-looking statements include statements about the enrollment and availability of patients under the amended NAPOLI-1 protocol, the design of MM-398 and the ability of MM-398 to favorably impact cancer patients. 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 on May 15, 2012.

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Source: Merrimack Pharmaceuticals

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