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Merrimack Pharmaceuticals Initiates Cross-Tumor Study to Investigate Potential Predictive Response Markers for a Developmental Nanotherapeutic Chemotherapy

Translational Study Examines Tissue and Imaging Based Biomarkers Across Indications

CAMBRIDGE, Mass., Dec. 19, 2012 (GLOBE NEWSWIRE) -- Merrimack Pharmaceuticals, Inc. (Nasdaq:MACK) today announced enrollment of its first patient in a cross indication translational study. The study is designed to identify predictive biomarkers associated with the novel compound MM-398 in advanced colorectal, lung and triple-negative breast cancers. Specifically, it aims to establish the feasibility of collecting specialized magnetic resonance-based images (MRI) and tissue-based biomarkers for the purpose of estimating drug delivery to the tumor and patient response to MM-398.

A stable, nanotherapeutic encapsulation of the chemotherapy irinotecan, MM-398 is designed to optimize the delivery of irinotecan by increasing levels of the drug deposited in the tumor, extending circulation and thereby enabling preferential activation of the therapy within the tumor. Preclinical research has shown that the length of time MM-398, specifically the active component, SN38, remains within tumors directly correlates with tumor response. Another key to MM-398's activity may be the number of macrophages within a tumor, which have been shown to preferentially internalize liposomes and release their contents.

"Our research indicates tumor micro-environments across these clinical indications allow for the deposition of large particles, such as nanotherapeutics. They also have high levels of tumor-associated macrophages, which means MM-398 can be broken down and release increased levels of chemotherapy to the adjacent cancer cells," said Ulrik Nielsen, Co-Founder and Chief Scientific Officer of Merrimack. "We believe this study is the first of its kind to combine the use of both imaging and biomarker diagnostic approaches and we hope that the insights we gain from this study will help to predict response to MM-398 in these hard-to-treat tumors."

The cross indication translational study will focus on patients that have progressed following standard of care therapy for colorectal, lung and triple-negative breast cancers. The study is taking place at Scottsdale Healthcare Medical Center in Arizona.

About MM-398

Merrimack initiated a pivotal Phase 3 clinical trial of MM-398 for the treatment of patients with metastatic pancreatic cancer who have previously failed treatment with gemcitabine. The trial, called NAPOLI-1 (NAnoliPOsomaL Irinotecan), is a global, randomized, open label Phase 3 study. NAPOLI-1 calls 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. Merrimack believes that MM-398 has potential uses in a number of other indications, including colorectal cancer, lung cancer, gastric cancer and glioma. In addition to NAPOLI-1, there are ongoing Phase 1 and Phase 2 clinical trials of MM-398 in glioma and colorectal cancer. 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.

In July 2011, the U.S. Food and Drug Administration (FDA) granted MM-398 orphan drug designation for the treatment of pancreatic 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.

About Merrimack Pharmaceuticals, Inc.

Merrimack Pharmaceuticals 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 six targeted therapeutic oncology candidates in clinical development.

Forward-Looking Statement

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 potential effectiveness of its drug candidates in new indications, the safety and tolerability of its drug candidates and its ability to translate clinical and pre-clinical data into future clinical success. 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 November 14, 2012 and other reports Merrimack files with the SEC.

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