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Merrimack Pharmaceuticals Completes Enrollment of Neoadjuvant Phase 2 Study of MM-121 in HER2-Negative Breast Cancer

CAMBRIDGE, Mass., Oct. 1, 2013 (GLOBE NEWSWIRE) -- Merrimack Pharmaceuticals, Inc. (Nasdaq:MACK) announced today that the last patient has been enrolled in the second cohort of a two-cohort randomized Phase 2 clinical trial of MM-121 in combination with paclitaxel in the neoadjuvant setting of HER2-negative breast cancer. MM-121, also known as SAR256212, is a fully human monoclonal antibody that targets ErbB3, a cell surface receptor implicated in tumor growth and survival, being developed in collaboration with Sanofi.

The Phase 2 study is designed to evaluate whether the combination of MM-121 with paclitaxel is more effective than treatment with paclitaxel alone when administered as part of a neoadjuvant treatment regimen in two patient cohorts of HER2-negative, locally advanced breast cancer patients. This second, fully enrolled cohort is comprised of 100 patients with triple negative breast cancer (TNBC), which is diagnosed when a patient's tumor has tested negative for HER2, estrogen receptor (ER) and progesterone receptor (PR) biomarkers. Final results from the second cohort are expected in 2014.

The first cohort of this Phase 2 study was fully enrolled in April 2013 and is comprised of 100 patients with tumors that are HER2-negative, but either ER and/or PR biomarkers are positive. Final results from the first cohort are expected in fall 2013.

"Completing enrollment in this study represents a significant milestone for Merrimack, as it is the fourth Phase 2 MM-121 study to be fully accrued, bringing enrollment in the Phase 2 MM-121 program to a total of 768 patients across the four studies in breast, ovarian and lung cancers," said William Kubasek, Ph.D., Vice President and MM-121 Project Leader at Merrimack Pharmaceuticals. "With pretreatment biopsies required in three of these studies, we believe that our translational clinical research program will provide the foundation to better understand the biomarkers associated with ErbB3 signaling, setting the stage for the next phase of development of MM-121."

Following treatment with either MM-121 and paclitaxel, or paclitaxel alone, patients from both groups will receive standard treatment with doxorubicin and cyclophosphamide and be monitored until surgical resection. The study is being conducted in the United States.

Sanofi and Merrimack entered into an exclusive, global license and collaboration agreement for MM-121 in 2009.

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. For more information, please visit Merrimack's website at www.merrimackpharma.com.

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-121 to provide clinical benefit, the ability of Merrimack to identify patients most likely to respond to treatment 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, 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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