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Merrimack Pharmaceuticals Presents Promising Phase I Clinical Data for Novel Agent to Treat HER2-positive Breast Cancer and Preclinical Data on Companion Diagnostic

Phase I Study Results Presented at the San Antonio Breast Cancer Symposium

CAMBRIDGE, Mass., Dec. 10, 2012 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (NASDAQ: MACK) today announced Phase I clinical trial results for MM-302, the company's novel agent for the treatment of advanced HER2 positive (HER2+ or ErbB2+) breast cancer. The findings demonstrated preliminary safety and tolerability. A study of its potential companion imaging diagnostic was shown to predict treatment response in preclinical models. Data were presented at the 2012 CTRC-AACR San Antonio Breast Cancer Symposium, Dec. 4-8, 2012 in San Antonio, Texas.

To view the multimedia assets associated with this release, please click http://www.prnewswire.com/news-releases/merrimack-pharmaceuticals-presents-promising-phase-i-clinical-data-for-novel-agent-to-treat-her2-positive-breast-cancer-and-preclinical-data-on-companion-diagnostic-182810031.html

MM-302 is a nanotherapeutic encapsulation of the anthracycline chemotherapy agent doxorubicin with anti-HER2 antibody fragments attached to its surface. Anthracyclines have known cardiotoxicities which historically have restricted their use in combination with HER2-targeted therapies.

"We are highly encouraged by these results. MM-302 was engineered to be a more effective treatment than free doxorubicin and to address the safety concerns associated with the traditional chemotherapy," said Ulrik B. Nielsen, Co-Founder and Chief Scientific Officer, Merrimack Pharmaceuticals. "We've encapsulated doxorubicin in a liposomal membrane that is designed to travel through the blood to the tumor cell with limited uptake into normal tissue such as heart tissue. When it arrives at the tumor cell, the antibodies on the outside of the encapsulated medicine bind to the HER2 receptor and pull the medicine inside the cell, allowing the chemotherapy to be delivered locally within the tumor."

Merrimack is developing an image-based companion diagnostic, MM-DX-929, to predict response to liposomal chemotherapeutics, such as MM-302. A preclinical study presented at SABCS showed that tumor uptake of MM-DX-929 correlated well with treatment response to MM-302.

METHODOLOGY AND RESULTS

A Phase I Study of MM-302, a HER2-targeted Liposomal Doxorubicin, in Patients with Advanced, HER2-positive (HER2+) Breast Cancer (Abstract #: P5-18-09)

- To evaluate the safety and tolerability of MM-302, 34 patients with histologically confirmed HER2+ metastatic breast cancer were enrolled. Patients had received a median of seven prior therapies. The study used a standard 3 + 3 dose escalation design to determine the Phase II dose of MM-302. Patients were enrolled across five dose levels ranging from 8 mg/m^2 to 50mg/m^2 given every 4 weeks.
- Overall MM-302 was well tolerated. The most frequent adverse events were fatigue (47%), nausea (41%) and decreased appetite (31%). Four patients had grade 3 or 4 toxicities. No dose limiting toxicities were observed and none of the patients treated thus far has had a decrease in cardiac ejection fraction.
- Of the 22 evaluable patients in this heavily pretreated patient population, 12 patients achieved stable disease (SD) and two patients achieved a partial response (PR), resulting in a clinical benefit rate of 64%. One of the patients who achieved a PR had a 100% regression of their target lesion.

A Novel 64Cu-Liposomal PET Agent (MM-DX-929) Predicts Response to Liposomal Chemotherapeutics in Preclinical Breast Cancer Models (Abstract #: P4-02-05)

- Preclinical models bearing BT474-M3 mammary and subcutaneous tumors were injected intravenously with MM-DX-929 prior to dosing with MM-302. PET/CT imaging was performed at 16 hours post MM-DX-929 injection, and tumor uptake was evaluated. Response to treatment was quantified as tumor volume changes measured over a 2-month period by MRI.
- Tumor deposition of MM-DX-929 correlated well with treatment response to MM-302 (Spearman correlation coefficient of -0.891 and a p-value of 0.0004). MM-DX-929 accumulation in tumors prior to the start of the MM-302 treatment successfully predicted improved tumor growth inhibition following MM-302 treatment.
- These findings support further development of MM-DX-929 as a potential diagnostic imaging agent to identify patients

who are most likely to respond to liposomal therapies.

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 five 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 safety and tolerability of its drug candidates and its ability to translate clinical and preclinical 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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