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Merrimack Pharmaceuticals Announces Initiation of HERMIONE, a Randomized Trial of MM-302 in Patients With Advanced HER2-Positive Breast Cancer to Support Application for Accelerated Approval

Trial is Recruiting Patients Previously Treated With Ado-Trastuzumab Emtansine (T-DM1) and Pertuzumab

CAMBRIDGE, Mass., Aug. 11, 2014 (GLOBE NEWSWIRE) -- Merrimack Pharmaceuticals, Inc. (Nasdaq:MACK) today announced the initiation of a global, open-label, randomized Phase 2 trial of MM-302, a HER2-targeted nanoliposomal encapsulation of doxorubicin, in combination with trastuzumab (Herceptin®) in patients with HER2-positive locally advanced or metastatic breast cancer. The trial was designed with input from the U.S. Food and Drug Administration (FDA) to support a potential accelerated approval application.

"While there have been new therapies approved in the HER2-positive setting, there is no standard of care for patients whose cancer progresses despite treatment with trastuzumab, T-DM1 and pertuzumab. In our experience to date, MM-302 has shown promising clinical activity and an acceptable safety profile in patients with metastatic breast cancer who have progressed on HER2-directed therapies. We are moving this trial forward with a goal of transforming the standard of care for this population," said Thomas Wickham, Ph.D., Vice President of Development and MM-302 Project Team Leader.

MM-302 is Merrimack's wholly owned, novel antibody-drug conjugated liposomal doxorubicin (an anthracycline chemotherapy) that targets and binds to HER2, a protein that when overexpressed can lead to the development and aggressive progression of breast cancer. Merrimack is pursuing this study based on encouraging results from an ongoing Phase 1 study showing a median progression free survival (PFS) benefit of 5.7 months in a heavily pretreated (median of 4 prior lines of therapy) population of 47 patients receiving a therapeutic dose of MM-302 (30 mg/m² or greater) alone or in combination with trastuzumab. Patients who had not received prior anthracycline-based chemotherapy treatment had a median PFS of 10.9 months and a 35% overall response rate. The most common adverse events in the Phase 1 study were fatigue, nausea and decreased appetite. Cardiac events, which is a side effect that has limited the use of anthracyclines, have been infrequent and none were serious adverse events (*3 out of 47 patients (6%) experienced declines in ejection fraction*).

The HERMIONE trial is expected to enroll approximately 250 patients who will be randomized (1:1) to receive either MM-302 and trastuzumab (Herceptin®) or chemotherapy of their physician's choice (capecitabine, gemcitabine or vinorelbine) and trastuzumab. Eligible patients for the HERMIONE trial must have received prior treatment with trastuzumab in any setting, and pertuzumab (Perjeta®) and ado-trastuzumab emtansine (T-DM1, Kadcyla®) in the locally advanced or metastatic setting, but have not been treated with an anthracycline-based regimen. The primary endpoint of the trial is PFS. Secondary endpoints include overall survival, objective response rate, safety and tolerability. Merrimack plans to conduct the trial at approximately 60 sites in the United States, Canada and Western Europe, and initial trial sites are now open to screen patients in the United States. For more information on this trial, please visit www.clinicaltrials.gov (Identifier: NCT02213744)

About MM-302

MM-302 is a novel antibody-drug conjugated liposomal doxorubicin that specifically targets cancer cells overexpressing the HER2 receptor. As a liposomal encapsulation of doxorubicin, MM-302 is designed to allow for the selective uptake of drug into tumor cells while limiting exposure to healthy tissues, such as those of the heart. In addition to the HERMIONE trial, MM-302 is being evaluated in an ongoing Phase 1 clinical trial. MM-302 is the second nanoliposomal product candidate in Merrimack's clinical pipeline, the first being MM-398.

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 seeks to gain a deeper understanding of underlying cancer biology through its systems biology-based approach and develop new insights, therapeutics and diagnostics to improve outcomes for cancer patients. Merrimack currently has six oncology therapeutics in clinical development and three additional candidates in late stage preclinical development. Merrimack's lead product candidate, MM-398, recently completed a Phase 3 trial in post-gemcitabine pancreatic cancer. Based on the results of this trial, Merrimack intends to file a New Drug Application for MM-398 in 2014. 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-302 to provide clinical benefit, the potential safety profile of MM-302, the potential for the HERMIONE trial to support an accelerated approval application to the FDA and the potential for MM-302 to transform the standard of care. 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 May 6, 2014 and other reports Merrimack files with the SEC.

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