Merrimack Doses First Patient in Randomized Phase 2 Clinical Study of MM-121 in Patients with Post-Menopausal Metastatic Breast Cancer

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CAMBRIDGE, Mass., Feb. 26, 2018 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (Nasdaq: MACK), a clinical-stage oncology company focused on biomarker-defined cancers, today announced that it has dosed the first patient in its SHERBOC study, a double-blind, placebo-controlled randomized Phase 2 clinical trial of MM-121 (seribantumab) in patients with heregulin-positive, hormone receptor-positive and HER2-negative post-menopausal metastatic breast cancer. MM-121 is a fully human monoclonal antibody that targets HER3 signaling and is designed to overcome cancer cells' resistance to the effects of anti-tumor therapies.

"The SHERBOC study will investigate the treatment of patients who have progressed on prior therapies, including cyclin-dependent kinase (CDK) inhibitors, and urgently need additional treatment options," said J. Marc Pipas, M.D., Merrimack's Senior Medical Director and Project Leader for MM-121. "This is a crucial next stage for MM-121's development program, which in prior studies has shown evidence of activity and tolerability in patients with heregulin-positive lung, ovarian and breast cancers. The initiation of enrollment in this study is a significant step forward for our clinical pipeline, and further advances our biomarker-driven, precision medicine approach to the treatment of cancer."

The global, multi-site, randomized Phase 2 study will assess progression-free survival of MM-121, in combination with fulvestrant, versus a placebo and fulvestrant. The study will enroll heregulin-positive, hormone receptor-positive and HER2-negative post-menopausal breast cancer patients who have progressed after one or two lines of prior systemic therapies for metastatic or locally advanced disease and have received prior CDK inhibitor-based therapy. Hormone receptor-positive and HER2-negative breast cancer comprises three quarters of all breast cancer diagnoses in the United States. [1]

This study complements several other studies previously initiated by Merrimack, including the ongoing SHERLOC study in patients with heregulin-positive non-small cell adenocarcinoma of the lung who have progressed on a platinum-containing regimen. That open label, randomized Phase 2 study assessing MM-121 in combination with docetaxel versus docetaxel alone is expected to deliver top-line data in the second half of 2018.

The first patient in the SHERBOC study was dosed at the UF Health Cancer Center at Orlando Health in the United States.

About MM-121

MM-121, also known as seribantumab, is Merrimack's wholly owned, fully human anti-HER3 (ErbB3) monoclonal antibody that targets phenotypically distinct heregulin-positive cancer cells within solid tumors. Heregulin-positive cancer cells are characterized by their ability to escape the effects of targeted, cytotoxic and anti-endocrine therapies. Identification of heregulin positive cancer cells by RNA-ISH may identify tumors at risk for rapid clinical progression. Seribantumab, when used in the combination setting, is designed to block the heregulin/HER3 signaling axis to make these cells more responsive to the effects of the combination therapy and deliver improved clinical outcomes.

About Merrimack

Merrimack is a biopharmaceutical company based in Cambridge, Massachusetts that is outthinking cancer to ensure that patients and their families live fulfilling lives. Its mission is to transform cancer care through the smart design and development of targeted solutions based on a deep understanding of cancer pathways and biological markers. All of Merrimack's development programs, including four clinical studies and six candidates in preclinical development, fit into its strategy of 1) understanding the biological problems it is trying to solve, 2) designing specific solutions and 3) developing those solutions for biomarker-selected patients. This three-pronged strategy seeks to ensure optimal patient outcomes. For more information, please visit Merrimack's website at www.merrimack.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, future revenues 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, among others, statements about the timing of availability of clinical trial data. 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, availability of funding sufficient for Merrimack's foreseeable and unforeseeable operating expenses and capital expenditure requirements, and other matters that could affect the availability or commercial potential of Merrimack's product 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 8, 2017 and the other reports Merrimack files with the SEC.

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[1] American Cancer Society. Breast Cancer Facts & Figures 2015-2016. Atlanta: American Cancer Society, Inc. 2015.

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