Merrimack Receives Orphan Drug Designation for MM-121 for the Treatment of Heregulin Positive Non-small Cell Lung Cancer

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CAMBRIDGE, Mass., Oct. 30, 2017 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (NASDAQ: MACK) today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to MM-121, its investigational drug candidate, for the treatment of heregulin positive non-small cell lung cancer. MM-121 (seribantumab) is a fully human monoclonal antibody designed to block tumor survival signals and enhance the anti-tumor effect of combination therapies by targeting the cell surface receptor HER3 (ErbB3) in patients with high expression of the biomarker heregulin.

"This is an important regulatory step forward for the clinical development of MM-121 in non-small cell lung cancer and we are pleased to have access to additional support from the FDA in this indication," said Sergio Santillana, M.D., MSc, Chief Medical Officer. "Merrimack is dedicated to designing and developing novel precision therapeutics that shape treatment strategies for patients, and our randomized Phase 2 clinical trial of MM-121 in heregulin positive non-small cell lung cancer is well underway. We look forward to expanding the development of MM-121 to a biomarker-selected population of breast cancer patients later this year."

The FDA's orphan drug designation is granted to drugs and biologics intended to treat rare diseases or conditions with a prevalence of fewer than 200,000 people in the U.S. This designation includes eligibility for a seven-year period of marketing exclusivity for MM-121 upon approval, as well as other development assistance and financial incentives.

MM-121 is currently being evaluated in the SHERLOC study, a global randomized Phase 2 study that will assess progression-free survival of MM-121 in combination with docetaxel versus docetaxel alone. The study is enrolling patients with heregulin positive non-small cell adenocarcinoma of the lung who have progressed after a platinum-containing regimen and may have received anti PD-1 or anti-PD-L1 therapy. Top-line data for the SHERLOC study are expected in the second half of 2018.

In addition, Merrimack will be evaluating MM-121 in the SHERBOC trial, a global randomized Phase 2, double-blind, placebo-controlled clinical study of MM-121 added to standard of care in patients with heregulin positive, hormone receptor positive, HER2 negative metastatic breast cancer. The first patient is expected to be dosed in the SHERBOC study by the end of 2017.

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 and potentially contribute to rapid clinical progression in patients whose tumor cells test positive for heregulin as detected by RNA-ISH. When used in the combination setting, seribantumab is designed to block the heregulin/HER3 signaling axis to make tumor cells more sensitive to the effects of the combination therapy.

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 in distinct indications 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 and the initiation of new clinical trials. 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 August 9, 2017 and the other reports Merrimack files with the SEC.

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