Merrimack Discontinues Phase 2 SHERLOC Study of MM-121 in Patients with Non-Small Cell Lung Cancer Due to Futility

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- MM-121 did not improve progression free survival (PFS) in patients with non-small cell lung cancer (NSCLC) -

- Company to provide pipeline review update on third quarter financial results call, November 7, 2018 -

CAMBRIDGE, Mass., Oct. 19, 2018 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (Nasdaq: MACK), a clinical-stage oncology company focused on biomarker-defined cancers, today announced the termination of the SHERLOC study, its randomized, open-label Phase 2 clinical trial evaluating MM-121 in combination with docetaxel in patients with heregulin positive NSCLC.

This decision was made in agreement with the Chair of the independent Data Safety Monitoring Board following an interim analysis that was triggered by the occurrence of 75% of events required for trial completion. In total, 88% (67/76) of required events were captured in this analysis, and while the safety profile was consistent with MM-121's previously reported safety profile, the data demonstrated that the addition of MM-121 to docetaxel did not improve PFS over docetaxel alone in this patient population. Since futility was observed, the decision has been made to terminate the study.

Based on these results, Merrimack is implementing a comprehensive review of its drug candidate pipeline, including assessing the impact of these results on the continued development of MM-121. MM-121 is also currently being evaluated in the SHERBOC study, a Phase 2 clinical trial evaluating MM-121 in combination with fulvestrant, versus fulvestrant alone, in patients with heregulin positive, hormone receptor positive, ErbB2 (HER2) negative, metastatic breast cancer.

"We are very disappointed by the outcome of this study, in particular for patients and families facing this difficult diagnosis," said Sergio Santillana, M.D., M.Sc., Chief Medical Officer of Merrimack. "We deeply appreciate the support from all investigators, patients and their families who participated in this trial. We also want to recognize our team's efforts and commitment to the development of MM-121 in non-small cell lung cancer over the past several years."

"Our ability to make a swift decision regarding these results is based on our development approach of testing our targeted therapies in biomarker-defined patient populations, which allows us to accelerate the timeframe needed to obtain clear data read-outs," said Richard Peters, M.D., Ph.D., President and Chief Executive Officer of Merrimack. "The data provide a definitive signal that MM-121 does not improve clinical outcomes for patients with non-small cell lung cancer and, in line with this efficient development strategy, we plan to look closely at the data as we assess the continued development of MM-121 and evaluate our pipeline more broadly."

Merrimack will provide an update on its pipeline and the results of its portfolio review on its third quarter 2018 financial results call on November 7, 2018, and plans to present observations from the SHERLOC study at a future medical oncology meeting.

AboutMerrimack's Phase 2 SHERLOC Study

The SHERLOC study was a global, randomized, biomarker-selected, open-label Phase 2 clinical trial of MM-121 in combination with docetaxel, versus docetaxel alone, in patients with heregulin positive NSCLC. The trial enrolled 109 patients with NSCLC, all of whom underwent a biomarker screen for high tumor expression of heregulin, the signal for the HER3 receptor that is prevalent in solid tumors. Patients were also required to have received a prior platinum-based therapy, as well as prior immunotherapy where available and clinically indicated.

The primary endpoint of the trial was progression-free survival, with objective response rate, time to progression and overall survival as key secondary endpoints. Merrimack initiated the SHERLOC study in February 2015 and completed enrollment in September 2018.

AboutMerrimack's Phase 2 SHERBOC Study

The SHERBOC study is a global, randomized, biomarker-selected, double-blind Phase 2 clinical trial of MM-121 in combination with fulvestrant, versus a placebo and fulvestrant, in patients with heregulin positive, hormone receptor-positive and HER2-negative post-menopausal metastatic breast cancer. The study is enrolling 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.

The primary endpoint of the trial is progression-free survival, with objective response rate, time to progression and overall survival as key secondary endpoints. Patient enrollment for the SHERBOC study was initiated in February 2018.

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 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 review of its drug candidate pipeline. 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 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 SEC on August 7, 2018 and the other reports Merrimack files with the SEC.

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