Merrimack Completes Enrollment in Randomized Phase 2 SHERLOC Study of MM-121 (seribantumab) in Non-Small Cell Lung Cancer (NSCLC)

September 6, 2018

CAMBRIDGE, Mass., Sept. 6, 2018 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (Nasdaq: MACK), a clinical-stage oncology company focused on biomarker-defined cancers, today announced that it has completed enrollment in its ongoing SHERLOC study, a Phase 2 clinical trial evaluating its lead investigational drug candidate, MM-121, in patients with heregulin positive NSCLC.

"We believe the robust clinical interest we have seen in the SHERLOC study reflects the significant unmet medical need among this patient population," said J. Marc Pipas, M.D., Merrimack's Senior Medical Director and Project Leader for MM-121. "With gratitude to our team and, of course, to investigators and patients for their commitment to advancing cancer care, we are pleased to have achieved this clinical milestone and look forward to reporting the results from this event-driven study in the coming months."

The SHERLOC study is 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 primary endpoint of the trial is progression-free survival, with objective response rate, time to progression and overall survival as key secondary endpoints. Under the current protocol amendment, 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. Merrimack continues to anticipate top-line data from this trial in the second half of 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.

In addition to the SHERLOC clinical trial, MM-121 is also being evaluated in the global, randomized, biomarker-selected, double-blinded, placebo-controlled, Phase 2 SHERBOC clinical trial of MM-121 in combination with fulvestrant, versus fulvestrant alone, in patients with heregulin positive, hormone receptor positive, ErbB2 (HER2) negative, metastatic breast cancer.

In November 2017, MM-121 was awarded orphan drug status by the U.S. Food and Drug Administration (FDA) for the treatment of heregulin positive NSCLC. This designation may lead to eligibility for a seven-year period of marketing exclusivity for MM-121 upon approval, as well as other development assistance and financial incentives.

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 three 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 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.

Contact:
Geoffrey Grande, CFA
617-441-7602
ggrande@merrimack.com

View original content:http://www.prnewswire.com/news-releases/merrimack-completes-enrollment-in-randomized-phase-2-sherloc-study-of-mm-121-seribantumab-in-non-small-cell-lung-cancer-nsclc-300707211.html

SOURCE Merrimack Pharmaceuticals, Inc.