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# FDA Grants Merrimack Fast Track Designation for Seribantumab (MM-121) in Non-small Cell Lung Cancer

CAMBRIDGE, Mass., July 6, 2016 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (Nasdaq: MACK) today announced that the U.S. Food and Drug Administration (FDA) has granted seribantumab, also known as MM-121, Fast Track designation for development in patients with heregulin-positive, locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has progressed following immunotherapy. Fast Track is a program designed by the FDA to facilitate and expedite the development and review of drugs that treat serious conditions and fill an unmet medical need. Merrimack is conducting the SHERLOC trial, a global clinical study of seribantumab in combination with docetaxel or pemetrexed in heregulin-positive patients with NSCLC that is designed to support a Biologics License Application to the FDA. Seribantumab is Merrimack's wholly owned, fully human monoclonal antibody that targets ErbB3.

"We are pleased that the FDA recognizes the importance of investigating a novel, biomarker-directed agent such as seribantumab for patients with locally advanced or metastatic NSCLC who have been previously treated with an immunotherapy," said Dr. Akos Czibere, Vice President, Clinical Development at Merrimack. "Heregulin-positive cancer cells are characterized by their ability to escape the effects of a broad range of cancer therapies and potentially contribute to accelerated disease progression. The SHERLOC trial is designed to advance the development of a much-needed treatment option for patients with heregulin-positive NSCLC after they progress on immunotherapies. This is important because we find that more than 50% of patients with NSCLC are heregulin-positive."

Heregulin-positive disease has been linked to rapid progression and poor prognosis in multiple types of cancer, including NSCLC. The higher the prevalence of heregulin-positive cancer cells in a tumor, the lower the anti-tumor effect of the chemotherapy. Seribantumab is designed to block heregulin-driven signaling and enhance the anti-tumor effect of the chemotherapy. Data from Merrimack's prior clinical studies have shown that standard-of-care therapy may be more effective and result in improved patient outcomes when combined with seribantumab. Merrimack is investigating the efficacy and safety of seribantumab plus standard-of-care therapy in the SHERLOC trial.

Lung cancer is the leading cause of cancer-related death in the United States. The American Cancer Society estimates that approximately 224,000 new cases of lung cancer (both small cell lung cancer and NSCLC) will be reported in 2016, 83% of which will be NSCLC[i]. Merrimack estimates that approximately 101,000 U.S. NSCLC patients will have heregulin-positive tumors, based on the prevalence seen in data presented by Merrimack at the 2014 European Society for Medical Oncology Congress[ii].

**About the SHERLOC Trial**

The SHERLOC trial is a randomized, open-label, multi-center, Phase 2 study in patients with heregulin-positive, locally advanced or metastatic NSCLC. Merrimack expects to enroll approximately 280 heregulin-positive patients who will be randomized (2:1) to receive seribantumab in combination with either docetaxel or pemetrexed versus docetaxel or pemetrexed alone. Patients will be screened for heregulin status using a fully validated RNA-ISH assay (in situ hybridization). Eligible patients for the study must have failed prior treatment with no more than three lines of therapy including prior anti-PD-1 or anti-PD-L1 immunotherapy. The study's primary endpoint is overall survival with secondary endpoints including progression free survival, objective response rate, safety and quality of life measures. The study is designed to support a Biologics License Application to the FDA with data expected in 2018. For more information on this trial, please visit www.clinicaltrials.gov (Identifier: NCT02387216).

**About Seribantumab (MM-121)**

Seribantumab is Merrimack's wholly owned, fully human anti-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/ErbB3 signaling axis in order to make these cells accessible to the effects of the combination therapy and potentially lead to significantly improved clinical outcomes.

Merrimack is also developing its novel heregulin assay for seribantumab into a kit for commercial use under a partnership agreement with Leica Biosystems.

**About Merrimack**

Merrimack is a fully integrated biopharmaceutical company that views cancer as a complex engineering challenge. Through systems biology, which brings together the fields of biology, computing and engineering, Merrimack aims to decrease uncertainty in drug development and clinical validation, and move discovery efforts beyond trial and error. Such an approach has the potential to make individualized treatment of patients a reality. Merrimack's first commercial product, ONIVYDE® (irinotecan liposome injection), was approved by the U.S. FDA in October 2015. With four additional candidates in clinical studies, several in preclinical development and multiple biomarkers designed to support patient selection, Merrimack is building one of the most robust oncology pipelines in the industry. For more information, please visit Merrimack's website at www.merrimack.com or connect on Twitter at @MerrimackPharma.

**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," and similar expressions. In this press release, Merrimack's forward-looking statements include, among others, statements about the potential effectiveness and safety profile of MM-121 in certain patient populations or subpopulations, the ability to use heregulin as a predictive diagnostic and the ability to translate clinical data into future clinical success. 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 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 2, 2016 and other reports Merrimack files with the SEC.

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[i] American Cancer Society; *2016 Facts & Figures.*

[ii] Heregulin prevalence (54%) from NSCLC Ph2 trial presented at ESMO 2014, applied to U.S. NSCLC annual incidence from American Cancer Society, 2016 (83% of U.S. lung cancer annual incidence of 224,390 patients)

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/fda-grants-merrimack-fast-track-designation-for-seribantumab-mm-121-in-non-small-cell-lung-cancer-300294237.html

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