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Final Analysis of First-in-Human Phase 1 Study of MM-151 Shows Positive Clinical Activity in Multiple Solid Tumor Types, Including Colorectal Cancer

Objective response observed in 21 percent of evaluable patients in the metastatic colorectal cancer (CRC) cohort; reduction in tumor size observed in 54 percent of patients in same cohort
Preliminary clinical activity in EGFR-treatment refractory and EGFR-treatment naïve populations, with median progression-free survival of four months in a heavily pre-treated CRC cohort, supports potential for broad clinical effect
MM-151 demonstrated an acceptable safety profile in heavily pre-treated patients

CAMBRIDGE, Mass., June 6, 2016 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (Nasdaq: MACK) today announced results from the final analysis of the Phase 1 study of MM-151, a novel investigational oligoclonal epidermal growth factor receptor (EGFR) inhibitor, in patients with refractory solid tumors. These results were presented at a Poster Discussion Session at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

Data from the Phase 1 study show positive clinical activity across multiple solid tumor types in a heavily pretreated patient population. Twenty-one percent of evaluable patients in the metastatic colorectal cancer (CRC) cohort achieved an objective response and 54 percent of patients showed a decrease in tumor size. A median progression-free survival (PFS) of four months was also observed within the CRC cohort. MM-151 also exhibited positive clinical activity in both EGFR-treatment refractory and EGFR-treatment naïve populations. These preliminary data support the potential for broad clinical effect, and demonstrate an acceptable safety profile consistent with existing EGFR therapies.

"We are excited to present the final analysis of the Phase 1 data of MM-151, Merrimack's novel oligoclonal EGFR-inhibitor," said J. Marc Pipas, M.D., Senior Medical Director at Merrimack. "The promising preliminary Phase 1 data highlights MM-151's ability to impair EGFR-driven signaling and overcome resistance, particularly in colorectal cancer patients. We are encouraged by these results given the unmet needs in this patient population, and we look forward to further evaluating this investigational therapy's potential to address this challenging disease."

CRC is the third most common cancer and is the second leading cause of cancer death in the United States. An estimated 144,000 new cases are expected to be diagnosed in 2016. The five-year survival rate for metastatic CRC is estimated at 11 percent.[i] The two most recent approved drugs for late stage metastatic CRC demonstrated objective response rates of less than two percent and PFS below two months in their clinical studies, while demonstrating an overall survival benefit versus best supportive care (no drug treatment)[ii] [iii].

Methodology and Results

This study evaluated MM-151 as a monotherapy and in combination with irinotecan. An expansion cohort was enrolled to evaluate clinical activity in EGFR-refractory metastatic CRC patients. Subset analyses and additional biomarker evaluations were performed in EGFR-driven indications. A total of 111 patients were treated with escalating dose levels; 87 patients on monotherapy and 24 patients receiving MM-151 in combination with irinotecan. The most common tumor types were CRC (45 [41%]), head and neck cancers (14 [13%]) and non-small cell lung cancer (11 [10%]).

Safety of MM-151

- MM-151 demonstrated a comparable safety profile to approved EGFR inhibitors as a monotherapy and in combination with irinotecan.
- Apart from infusion reactions, which occurred at decreasing frequency and severity as the dosing schedule was

modified over the course of the study, the most common adverse events reported were rash, hypomagnesemia, fatigue and diarrhea in the monotherapy cohorts. These adverse events were expected and consistent with EGFR inhibition class toxicities.

Results

- Preliminary indications of clinical activity with MM-151, across both the EGFR-refractory and naïve populations, suggest there is potential for broad effect.
- Biomarker profiling suggests MM-151 may overcome mechanisms of resistance.
- Preliminary data in the CRC subset show 54 percent of evaluable patients had a reduction in tumors. Forty-five percent (13/29) of patients in the CRC subset achieved stable disease or partial response at three cycles of treatment and 17 percent (5/29) achieved a partial response, with highly durable responses and disease control.
- Preliminary biomarker analysis of blood samples ("liquid biopsies") following MM-151 treatment show low occurrence of acquired KRAS/NRAS/BRAF mutations in the CRC cohort and no occurrence of acquired EGFR extracellular domain mutations, which have been reported to mediate resistance to cetuximab and panitumumab.
- A median PFS of four months was observed in the CRC cohort.
- Observations in exploratory biomarker analyses are consistent with the multiple mechanisms of action that have been previously described for MM-151 in preclinical studies, including EGFR downregulation, expression of high-affinity EGFR ligands across indications (including refractory metastatic CRC) and activity in tumors expressing EGFR and downstream mutations.
- Further clinical evaluation is underway.

About MM-151

Merrimack used its systems biology approach to engineer MM-151, an oligoclonal therapeutic that is a mixture of three fully human monoclonal antibodies designed to bind and inhibit signaling of EGFR. EGFR-mediated signaling promotes the growth and survival of cancer cells and is recognized as an important drug target in several types of cancer, including colon, lung, breast, pancreatic and head and neck cancers. The use of three antibodies maximizes receptor inhibition, and provides mechanisms to overcome resistance to EGFR-targeted therapies. MM-151 is also being evaluated in two other Phase 1 studies; one in combination with the ONIVYDE® (irinotecan liposome injection) regimen for metastatic CRC, and another in a first-of-its-kind, multi-arm basket study in combination with three other novel agents, two of which are from Merrimack's oncology pipeline. Merrimack initiated these studies in May.

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-151 in certain patient populations or subpopulations 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 and Figures.

[ii] Van Cutsem E, Sobrero AF, Siena S, et al. Phase III CORRECT trial of regorafenib in metastatic colorectal cancer (mCRC). J Clin Oncol. 2012;30(suppl; abstr 3502).

[iii] Mayer RJ, Van Cutsem E, Falcone A, et al. Randomized Trial of TAS-102 for Refractory Metastatic Colorectal Cancer. NEJM. 2015;372:1909-1919.