Merrimack Announces Top-Line Results from Randomized Phase 2 Trial of MM-141 in Front-Line Metastatic Pancreatic Cancer

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- CARRIE study did not meet primary or secondary endpoints -
- Company ceases development of MM-141 -
- Focus remains on advancing Merrimack's promising clinical and preclinical pipeline, with two additional clinical study readouts anticipated in 2H 2018 -

CAMBRIDGE, Mass., June 25, 2018 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (Nasdaq: MACK), a clinical-stage oncology company focused on biomarker-defined cancers, today announced top-line results from the CARRIE study, a randomized Phase 2 trial evaluating the addition of MM-141 (istiratumab) to standard-of-care treatment in patients with previously untreated metastatic pancreatic cancer and high serum levels of free Insulin-like Growth Factor-1 (IGF-1). The study did not meet its primary or secondary efficacy endpoints in patients who received MM-141 in combination with nab-paclitaxel and gemcitabine, compared to nab-paclitaxel and gemcitabine alone. These results were consistent in all subgroups analyzed. Based on these results, Merrimack will not devote additional resources to the development of MM-141.

Merrimack plans to present the complete data from this Phase 2 study at an upcoming medical oncology meeting.

"Pancreatic cancer is the third leading cause of cancer-related death in the Unites States and a very difficult cancer to treat," said Sergio Santillana, M.D., MSc., Chief Medical Officer of Merrimack. "Although we were unsuccessful in our effort to improve the standard of care for these patients, we want to express our gratitude to our investigators and our team, and, of course, to the patients and their families for their support and participation in the CARRIE study."

"While these results are disappointing, looking forward our focus remains on the continued development of our deep, wholly-owned pipeline, including two clinical programs, MM-121 and MM-310, with data readouts expected in 2018," said Richard Peters, M.D., Ph.D., President and CEO of Merrimack.

MM-121 (seribantumab), a monoclonal antibody targeting the HER3 (ErbB3) receptor, is being tested in combination with standard-of-care treatment in two randomized Phase 2 studies: SHERLOC, in patients with non-small cell lung cancer, and SHERBOC in patients with metastatic breast cancer. Both studies are enrolling patients with high tumor expression of heregulin, the signal for the HER3 receptor. Top-line results from the SHERLOC study are expected in 2H 2018.

MM-310, an antibody-directed nanotherapeutic targeting the EphA2 receptor, is currently being tested in a Phase 1 study in solid tumors, with safety data and the maximum tolerated dose expected in 2H 2018.

About Merrimack's Phase 2 CARRIE Study

The CARRIE study is a global, double-blinded, placebo-controlled, randomized Phase 2 trial, evaluating MM-141 in patients with previously untreated metastatic pancreatic cancer. Prior to enrollment, patients were screened for high serum levels of free IGF-1, a prevalent biomarker in approximately 50% of patients with pancreatic cancer that is believed to be associated with more aggressive forms of the disease. The trial enrolled 88 patients who were randomized 1:1 to treatment and control arms to assess MM-141, in combination with the standard-of-care chemotherapy (nab-paclitaxel and gemcitabine), versus chemotherapy plus placebo. The primary endpoint of the study is progression-free survival, while secondary endpoints include objective response rate, disease control rate, duration of response, overall survival and safety. Merrimack initiated the CARRIE study in May 2015 and completed enrollment in June 2017.

About MM-141

MM-141 (istiratumab) is Merrimack's wholly owned, fully human, bispecific, tetravalent monoclonal antibody, targeting receptor complexes containing the Insulin Like Growth Factor 1 Receptor (IGF-1R) and ErbB3 (HER3) cell surface receptors to block tumor survival signals. IGF-1R and HER3 complexes cooperate to activate the PI3K/AKT/mTOR pathway, a major signaling pathway that allows tumor cells to grow and develop resistance to chemotherapy. MM-141 is designed to suppress the PI3K/AKT/mTOR pathway by binding to both the IGF-1R and HER3 receptors.

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 use of Merrimack's resources and 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 May 8, 2018 and the other reports Merrimack files with the SEC.

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