October 2, 2012

Merrimack Pharmaceuticals' Therapies Show Promise In Certain Advanced Breast, Gastric And Gynecologic Cancers

Phase 1 Study Results Presented at ESMO 2012 Congress Show ErbB3 as Potential Therapeutic Target

CAMBRIDGE, Mass., Oct. 2, 2012 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (NASDAQ: MACK) today announced the presentation of Phase 1 safety and clinical results evaluating two potential new therapies with a novel target — ErbB3, a signaling receptor believed to be responsible for triggering tumor growth and resistance in a number of malignancies including breast, ovarian, gastric, esophageal and bladder cancers. The two studies were presented in poster sessions at the European Society for Medical Oncology (ESMO) in Vienna, Austria.

To view the multimedia assets associated with this release, please click: http://www.multivu.com/mnr/58387-merrimack-pharmaceuticals-erbb3-cancer-therapy-esmo-2012-congress

The separate studies were testing the safety profiles of (1) MM-121, developed in collaboration with Sanofi, in a combination regimen with weekly paclitaxel in advanced metastatic breast and ovarian cancers and (2) MM-111 in multiple HER2-Targeting regimens in advanced HER2 positive (ErbB2+ or HER2+) solid tumors. Each study demonstrated a promising clinical benefit rate for the MM-121 and MM-111 combination regimens, a secondary endpoint for each of the studies. MM-121 and MM-111 each employ their own unique mechanisms to stop ligand-driven activation of ErbB3 from signaling the cancer cell to grow.

"We are pleased to see signs of clinical benefit in our studies with MM-121 and MM-111 across a broad range of solid tumors in patients who have progressed on standard of care therapies," said Robert J. Mulroy, President and Chief Executive Officer, Merrimack Pharmaceuticals. "Both candidates emerged from our Network Biology research engine, in which we identified ErbB3 as a central growth signaling node. Given their unique approaches to targeting ErbB3 biology, we believe that MM-121 and MM-111 are important therapies to advance the treatment of cancer and we are excited to watch them progress through clinical development."

A Phase 1 Study of the Anti-ErbB3 Antibody MM-121 in Combination with Weekly Paclitaxel in Patients with Advanced Gynecologic and Breast Cancers (Abstract #: 974PD)

The study evaluated MM-121, a fully human monoclonal antibody, in combination with weekly paclitaxel, a standard regimen for patients with advanced gynecological and metastatic breast cancers.

In partnership with Sanofi, this combination regimen is currently being evaluated in two phase 2 studies, one in advanced ovarian cancer and one in neoadjuvant breast cancer.

Methodology & Results

- A total of 28 patients with certain platinum resistant gynecological cancers or HER2 non-overexpressing breast cancer received a combination of MM-121 and weekly paclitaxel until disease progression or intolerable toxicity was reported. Response was assessed every eight weeks.
- The observed safety profile of MM-121 in combination with weekly paclitaxel suggest a similar toxicity profile to that of weekly paclitaxel alone.
- **Across all dosing cohorts, the overall clinical benefit rate was 70 percent. Forty-eight percent achieved a partial response (PR) and of those, 39 percent achieved a confirmed PR with a median duration of 2.7 months (range 1.7 — 15.1 months). Twenty-two percent experienced stable disease (SD) > 4 months with a median duration of 5.3 months. Nine percent of patients had progressive disease (PD) at first assessment and 26 percent remain on study with a median on-study time of 13.5 months in 23 evaluable patients.**

A Phase 1 Study of MM-111; a Bispecific HER2/HER3 Antibody Fusion Protein, Combined with Multiple Treatment Regimens in Patients with Advanced HER2 Positive Solid Tumors (Abstract #: 496P)

The Phase 1, multi-arm study examined the safety, pharmacokinetics and anti-tumor activity of MM-111, a bispecific antibody targeting the HER2/HER3 complex, combined with the standard of care HER2-targeting regimens of capecitabine, cisplatin and trastuzumab ; lapatinib +/- trastuzumab; and paclitaxel with trastuzumab. The study included patients with breast, gastric, esophageal and bladder cancers.

"This study shows that HER3 may indeed play an important role in the growth and resistance of multiple HER2+ solid tumor types," said Donald A. Richards, M.D., Ph.D., medical oncologist with Texas Oncology—Tyler, an affiliate of The US Oncology Network. "This study suggests that MM-111 can be safely combined with several trastuzumab-containing regimens."

Phase 2 studies will further examine the role of MM-111 in the treatment of a variety of tumors, the first of which is expected to be initiated late this year.

Methodology & Results

- This was a multi-arm Phase 1 study in which MM-111 was combined with commonly used HER2-targeting regimens. Each arm of the study ran as a separate Phase 1 using standard 3+3 dose escalation. Safety, Tolerability, PK and responses were evaluated.
- A total of 46 patients with documented advanced HER2 + cancer received weekly doses of MM-111 at 10 mg/kg and escalated up to 20 mg/kg.
- MM-111 was tolerable and could be safely combined at full dose with lapatinib / trastuzumab and paclitaxel / trastuzumab regimens. The capecitabine containing arm required dose reduction of capecitabine. Re-escalation of MM-111 is ongoing.
- The toxicity profile of the MM-111 combinations was consistent with that generally observed in patients receiving the underlying HER2 therapy.
- **Across all dosing regimens, the overall clinical benefit rate, defined as complete response (CR), partial response (PR) and stable disease (SD) for at least 4 months, was 52 percent in 29 evaluable patients.**
- **Responses were observed across various tumor types including, breast, bladder, esophageal, colorectal and ovarian cancers.**

About Network Biology

Network Biology is a Merrimack Pharmaceuticals' proprietary, multidisciplinary approach to drug discovery and development, efficiently combining biology and mathematical modeling to understand the complex network, or molecular web of signaling pathways, within a cancer cell and the relationship between switches that turn specific processes on and off, triggering cell growth. Merrimack utilizes this information to develop medicines to disrupt or alter cancer growth signaling and to develop diagnostics to identify which patients will benefit most from each treatment. Network Biology is highly efficient and has the potential to significantly quicken the pace of drug discovery and development for not just cancer, but a multitude of serious diseases.

About Merrimack Pharmaceuticals, Inc.

Merrimack Pharmaceuticals is a biopharmaceutical company discovering, developing and preparing to commercialize innovative medicines paired with companion diagnostics for the treatment of serious diseases, with an initial focus on cancer. Merrimack applies Network Biology, its proprietary systems biology-based approach to biomedical research, throughout the research and development process. Merrimack currently has five targeted therapeutic oncology candidates in clinical development.

Forward-Looking Statement

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," "suggests, ""continue," and similar expressions. In this press release, Merrimack's forward-looking statements include statements about the safety, activity and benefits of MM-121 in combination with paclitaxel and of MM-111 in combination with certain HER2-targeting regimens. 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 and conduct of future clinical trials, availability of data from ongoing clinical trials, the results of future clinical trials, expectations for regulatory approvals, development progress of Merrimack's companion diagnostics, 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 Form 10-Q filed with the Securities and Exchange Commission on August 14, 2012, available on the investor relations portion of the Company's website at http://www.merrimackpharma.com and on the SEC's website at http://www.sec.gov.

SOURCE Merrimack Pharmaceuticals, Inc.