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Merrimack Pharmaceuticals Announces MM-398 Achieves Primary Endpoint of Overall Survival in Phase 3 Trial in Post-Gemcitabine Metastatic Pancreatic Cancer

MM-398 in combination with 5-fluorouracil and leucovorin demonstrates statistically significant advantage compared to control arm

Plan to submit New Drug Application in 2014

Conference Call Scheduled for 8:30 a.m. ET Today

CAMBRIDGE, Mass., May 1, 2014 (GLOBE NEWSWIRE) -- Merrimack Pharmaceuticals, Inc. (Nasdaq:MACK) today announced that the combination of MM-398 with 5-fluorouracil (5-FU) and leucovorin achieved an overall survival of 6.1 months, a 1.9 month improvement over the 4.2 month survival demonstrated by the control arm of 5-FU and leucovorin alone. The NAPOLI-1 Phase 3 study was conducted in patients with metastatic pancreatic cancer who previously received gemcitabine-based therapy. The primary log-rank analysis of overall survival was statistically significant ($p=0.012$) with a corresponding hazard ratio of 0.67. A statistically significant advantage for progression free survival was also observed in the combination arm.

The most common Grade 3 or higher adverse events in the combination arm were neutropenia (14.5%), fatigue (13.7%), diarrhea (12.8%) and vomiting (11.1%). Sepsis (3.4%) was the only serious life threatening event that occurred with a more than 2% difference between the combination arm and the control arm.

"We are excited by the results of the NAPOLI-1 study because of the critical need to help patients with this devastating illness and are moving forward as quickly as possible to get MM-398 to patients," said Robert Mulroy, President and CEO of Merrimack. "Given that there have only been a handful of successful Phase 3 trials in pancreatic cancer in the past 25 years, it is gratifying to have the first positive Phase 3 trial in the post-gemcitabine setting. The results reinforce our confidence in our entire nanoliposomal pipeline. We are grateful for the dedication of the investigators, the research community and, most importantly, the patients and their families who bravely participated in this study."

The Phase 3 study also examined MM-398 in a monotherapy regimen. MM-398 had a 4.9 month median overall survival as a monotherapy, but did not achieve a statistically significant survival advantage compared to the 4.2 months in the control arm. The hazard ratio for overall survival was 0.99 with a corresponding p-value of 0.942. In general, patients experienced a higher level of adverse events with the MM-398 monotherapy dose and treatment schedule compared to patients who received the combination of MM-398 with 5-FU and leucovorin.

"This demonstration of a survival benefit from the MM-398 plus 5-FU and leucovorin combination is particularly important given that we have very few treatment options for patients in this tough clinical setting," said Daniel D. Von Hoff, M.D., F.A.C.P., global principal investigator of the NAPOLI-1 study, Chief Scientific Officer for Scottsdale Healthcare's Virginia G. Piper Cancer Center and Distinguished Professor at Translational Genomics Research Institute (TGen).

"The Pancreatic Cancer Action Network's goal is to double pancreatic cancer survival by 2020. The positive results of this trial demonstrate progress toward that goal in a disease for which additional treatment options are urgently needed to improve patient outcomes," stated Julie Fleshman, President and CEO of the Pancreatic Cancer Action Network. "These results also underscore the important role clinical trials play when patients are exploring their treatment options. We applaud Merrimack's dedication to improving the treatment landscape for this patient population, and helping us charge forward in the fight against pancreatic cancer."

This study has been accepted for oral presentation at the European Society for Medical Oncology World Conference on Gastrointestinal Cancer being held in Barcelona, Spain on June 25-28, 2014. Merrimack expects to submit a New Drug Application to the U.S. Food and Drug Administration for the MM-398 combination regimen in 2014.

NAPOLI-1 Trial Design

NAPOLI-1 (NAnoliPOsomaL Irinotecan) is a randomized, open label Phase 3 study in patients with metastatic pancreatic cancer who received prior gemcitabine-based therapy. The study evaluated two MM-398 regimens, 80 mg/m² combined with 5-FU and leucovorin every two weeks, and 120 mg/m² as a monotherapy every three weeks. Each arm was compared to a control arm of 5-FU and leucovorin. A total of 417 patients were randomized across the three arms. Each MM-398 regimen was compared against the control arm on the primary endpoint of overall survival. Patients were enrolled at over 100 sites in North America, South America, Europe, Asia and Australia.

Merrimack to Host Conference Call

Merrimack will conduct a live conference call and webcast today, Thursday, May 1 at 8:30 a.m., Eastern Time, to discuss these top line results and provide a summary of first quarter 2014 financial results. Investors and the general public are invited to listen to the call by dialing (877) 564-1301¹ (domestic) or (224) 357-2394¹ (international) five minutes prior to the start of the call and providing the passcode 37032608. A listen-only webcast of the call can be accessed in the Investors section of Merrimack's website, <http://investors.merrimackpharma.com>, and a replay of the call will be archived there for six weeks following the call.

About MM-398

MM-398 (irinotecan liposome injection), also known as "nal-IRI," is a nanoliposomal encapsulation of the chemotherapeutic irinotecan. MM-398 has demonstrated extended circulation in comparison to free irinotecan in the clinical setting. The activated form of irinotecan is SN-38, which functions by inhibiting topoisomerase I (an essential enzyme involved in DNA transcription and replication) and promoting cell death.

MM-398 is an investigational agent which is also currently being evaluated in an ongoing Phase 2 study in patients with metastatic colorectal cancer and Phase 1 studies in Ewing's sarcoma and glioma. An additional Phase 1 clinical trial is assessing a potential companion diagnostic for MM-398 in patients with multiple cancer types to determine which patients are most likely to benefit from treatment with the drug.

Under a 2011 agreement with PharmaEngine, Inc. (Taipei, Taiwan), Merrimack consolidated the worldwide development and commercialization rights to MM-398, with PharmaEngine, Inc. retaining commercialization rights in Taiwan.

MM-398 is not approved for any indication by the U.S. Food and Drug Administration (FDA) or any other regulatory agency. Both the FDA and the European Medicines Agency have granted MM-398 orphan drug designation in metastatic pancreatic cancer.

About Pancreatic Cancer

In the United States alone, approximately 46,000 people are diagnosed with pancreatic cancer and about 40,000 patients die annually, making it the fourth most common cause of cancer death. The one year and five year mortality rates are 73 percent and 94 percent, respectively¹. Because the signs and symptoms of pancreatic cancer may not appear until the disease has spread to other sites in the body, a majority of patients are not candidates for surgery and receive chemotherapy as the mainstay of their therapy. There is no consensus on the standard of care for metastatic pancreatic cancer patients previously treated with a gemcitabine-based therapy.

About Merrimack

Merrimack is a biopharmaceutical company discovering, developing and preparing to commercialize innovative medicines paired with companion diagnostics for the treatment of cancer. Merrimack seeks to gain a deeper understanding of underlying cancer biology through its systems biology-based approach and develop new insights, therapeutics and diagnostics to improve outcomes for cancer patients. Merrimack currently has six oncology therapeutics in clinical development and three additional candidates in late stage preclinical development. For more information, please visit Merrimack's website at www.merrimackpharma.com.

¹ American Cancer Society. *Cancer Facts and Figures 2014*. Atlanta: American Cancer Society; 2014.

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," "hope" and similar expressions. In this press release, Merrimack's forward-looking statements include statements about the potential effectiveness and safety profile of MM-398 either alone or in combination and the expected timeline for seeking regulatory approval for the MM-398 combination regimen. 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, availability of data from ongoing 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 4, 2014 and other reports Merrimack files with the SEC.

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