



August 13, 2013

Merrimack Pharmaceutical's MM-111 Granted Orphan Drug Status by FDA For Treatment of Advanced Gastric and Esophageal Cancers

CAMBRIDGE, Mass., Aug. 13, 2013 (GLOBE NEWSWIRE) -- Merrimack Pharmaceuticals, Inc. (Nasdaq:MACK) today announced that the U.S. Food and Drug Administration's Office of Orphan Products Development has granted two separate orphan drug designations for its bispecific antibody, MM-111, for the treatment of esophageal cancer and for the treatment of gastric as well as gastroesophageal junction (GEJ) cancers.

"We are pleased that the FDA has granted orphan status designation for the development of MM-111 in these two indications," said Victor Moyo, MBChB., Vice President of Clinical Investigations at Merrimack Pharmaceuticals. "Patients with HER2-expressing gastric and esophageal cancers have limited treatment options. We are excited to move forward with the development of MM-111 and hope to positively impact the lives of these patients by addressing an unmet medical need."

MM-111 is designed to inhibit ErbB3 (HER3) receptor signaling in cancers that overexpress ErbB2 (HER2). Overexpression of the ErbB2 cell surface receptor has been reported in 7-34 percent of gastric cancers according to various scientific articles. Research has shown that ErbB3 expression is associated with poor prognosis in gastric cancer and may contribute to resistance to some current standard treatments. Currently, MM-111 is being tested in a Phase 2 study in advanced gastric, esophageal and gastroesophageal junction cancers.

These two orphan drug designations will potentially provide Merrimack Pharmaceuticals with 7-year marketing exclusivity for MM-111 and other benefits if the drug is approved by the FDA. The FDA's Office of Orphan Products Development is dedicated to supporting the development of products that are promising for treatment and diagnoses of diseases that affect less than 200,000 Americans annually.

About Merrimack Pharmaceuticals, Inc.

Merrimack is a biopharmaceutical company discovering, developing and preparing to commercialize innovative medicines paired with companion diagnostics for the treatment of cancer. Merrimack applies its systems biology-based approach to biomedical research throughout the research and development process. Merrimack currently has six oncology therapeutics in clinical development.

Forward-Looking Statement

Any statements in this press release about future expectations, plans and prospects for Merrimack constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements in this press release include statements about the potential for MM-111 to provide clinical benefit and to achieve regulatory approval. Forward-looking statements involve substantial risks and uncertainties, and actual results may differ materially from those indicated by such forward-looking statements. Merrimack anticipates that subsequent events and developments will cause its views to change. However, while Merrimack may elect to update these forward-looking statements at some point in the future, Merrimack specifically disclaims any obligation to do so.

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Source: Merrimack Pharmaceuticals

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