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Merrimack Initiates Phase 2 Clinical Study of MM-111 in Advanced Gastroesophageal Cancers

Study Examines Safety and Efficacy of Bispecific Antibody in Two Subsets of Gastroesophageal Cancer Patients

CAMBRIDGE, Mass., July 22, 2013 (GLOBE NEWSWIRE) -- Merrimack Pharmaceuticals, Inc. (Nasdaq:MACK) today announced the enrollment of its first patient in a Phase 2 clinical trial of its bispecific antibody, MM-111, for the treatment of advanced gastric, esophageal and gastroesophageal junction (GEJ) cancers.

Overexpression of the HER2 (ErbB2) cell surface receptor has been reported in 7-34 percent of stomach and esophageal cancers. The HER2 receptor triggers tumor growth and survival when it binds together with an additional receptor known as HER3 (ErbB3) and another protein called heregulin. HER3 expression has been associated with poor prognosis in gastric cancer. MM-111 is designed to anchor to both receptors, HER2 and HER3, on the cell surface and block heregulin's ability to transmit tumor growth signals, thus inhibiting the tumor cell's ability to thrive.

This Phase 2 study is unique in that it is testing MM-111 in two different subsets of patients overexpressing the HER2 receptor:

- The first set of patients traditionally receive trastuzumab-based therapy due to their HER2 score of 2+ or 3+ on the HercepTest® and/or have a positive fluorescence in situ hybridization status (FISH+). These patients will be randomized to receive either MM-111 combined with paclitaxel and trastuzumab or paclitaxel and trastuzumab.
- The second set of patients in the study are usually not treated with HER2-targeted therapy because they have a HER2 2+ HercepTest® score and have a negative FISH status (FISH-) for the HER2 gene. Some of these patients may still have relatively high HER2 levels but there are currently no HER2-targeted therapy options available for them. These patients will be randomized to receive either MM-111 combined with paclitaxel or paclitaxel alone.

"This Phase 2 study in advanced gastric, esophageal and GEJ cancers addresses two distinct HER2-expressing patient populations with unmet needs who are often limited in their chemotherapeutic and targeted therapy options. This is especially true for those patients with HER2 HercepTest® scores of 2+, who are not eligible for HER2-targeted therapy," said Ulrik Nielsen, PhD, Co-Founder and Chief Scientific Officer of Merrimack. "We are excited to further examine MM-111's potential to delay resistance and restore sensitivity to standard of care treatments in this aggressive disease."

In preclinical research, MM-111 has shown activity in HER2+ cancer models that qualify for currently approved HER2-targeted treatments, as well as tumor cells that are not traditionally considered HER2+ but still have relatively high levels of the receptor (HER2 2+/FISH-).

This study is designed to evaluate whether MM-111 is safe and efficacious in both subsets of gastric, esophageal and GEJ cancer patients expressing the HER2 receptor. The first patient was enrolled at Fox Chase Cancer Center in Philadelphia, Pennsylvania. Up to 60 sites are expected to be opened in the United States, Europe, Asia and Africa.

For more information on these studies, please visit www.clinicaltrials.gov.

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. 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.

CONTACT: Media Contacts:

Kathleen Petrozzelli Gallagher,

Merrimack,

617-441-1043, kgallagher@merrimackpharma.com

Liz Bryan,

Spectrum,

202-955-6222, lbryan@spectrumscience.com

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