October 31, 2016

Merrimack Announces Acceptance for Review of ANDA filed by Actavis for Generic Doxorubicin Hydrochloride Liposome Injection (aka DOXIL®)

Acceptance further validates Merrimack's leadership in development and manufacturing of complex liposomal formulations
Profit share could meaningfully improve Merrimack's earnings

CAMBRIDGE, Mass., Oct. 31, 2016 /PRNewswire/ -- Merrimack Pharmaceuticals, Inc. (NASDAQ: MACK) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Abbreviated New Drug Application (ANDA) for generic doxorubicin hydrochloride (HCl) liposome injection submitted by its partner Actavis LLC (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.). This is the first product developed by Merrimack under a partnership agreement with Actavis LLC pursuant to which Merrimack is responsible for the development and commercial supply of bulk drug product and Actavis LLC is responsible for fill/finish activities, regulatory approvals and commercialization in the United States.

Doxorubicin HCl liposome injection is marketed as DOXIL® in the United States by Janssen Products LP, a Johnson & Johnson company. The approved indications for the product are ovarian cancer, AIDS-related Kaposi's sarcoma and multiple myeloma. DOXIL generated approximately $600 million annually in global revenue prior to Johnson & Johnson's 2011 manufacturing disruption, which resulted in the placement of DOXIL on the FDA's drug shortage list. While DOXIL was on the drug shortage list, the FDA approved a generic version of doxorubicin HCl liposome injection marketed by Sun Pharma Global FZE, and both products now share the U.S. market. If approved, Merrimack is eligible to receive a royalty rate in the mid-twenties of net profits on sales of doxorubicin HCl liposome injection under the agreement with Actavis.

"We are pleased to have achieved this important milestone with our partner, Actavis," said Gary Crocker, Chairman of Merrimack's Board of Directors and interim President and CEO. "This collaboration leverages Merrimack's proven expertise in the development of liposomal products and provides the opportunity to maximize the use of our state-of-the-art commercial liposomal manufacturing facility. It also could allow us, if the product is approved, to generate an additional revenue stream to not only offset costs but meaningfully improve earnings. We look forward to the FDA's review of Actavis's ANDA filing and providing further support as Actavis navigates the regulatory approval process."

Merrimack is a leader in the development and manufacturing of nanoliposomal products. In addition to the generic doxorubicin HCl liposome injection for which the ANDA was just accepted, Merrimack has developed or is developing several novel therapeutic candidates. Merrimack's first commercial product, ONIVYDE® (irinotecan liposome injection), is a novel liposomal formulation of irinotecan that was approved by the FDA in the United States in October 2015.

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 Merrimack's ability to develop future liposomal products, potential future revenue streams and potential improvement to earnings. Such forward-looking statements involve substantial risks and uncertainties that could cause Merrimack's 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 of future clinical

trials, 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 products, 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 Securities and Exchange Commission (SEC) on August 4, 2016 and other reports Merrimack files with the SEC.

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