Merrimack Provides Ipsen Report of Results From Phase III RESILIENT Trial Evaluating Onivyde® in Second-Line Monotherapy for Small Cell Lung Cancer

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 3, 2022-- Merrimack Pharmaceuticals, Inc. (Nasdaq: MACK) [("Merrimack" or the "Company")] announced that Ipsen, SA ("Ipsen") has issued a press release today reporting its primary analysis of the results of its Phase 3 trial of Onivyde® (irinotecan liposomal injection) as a treatment of second line small cell lung cancer (SCLC). The press release indicates that the "the primary endpoint OS was not met in patients treated with Onivyde versus topotecan. However, a doubling of the secondary endpoint of objective response rate (ORR) in favor of Onivyde was observed. The safety and tolerability of Onivyde was consistent with its already-known safety profile, and no new safety concerns emerged. The clinical study results will be communicated with the regulatory agency." Ipsen indicated in its update that it will analyze the data further before making decisions about next steps.

"We will continue to monitor updates from Ipsen regarding the SCLC program," said Gary Crocker, Chairman and CEO of Merrimack Pharmaceuticals. "Ipsen also reported in its recent H1 2022 financial results update provided on July 29, 2022, that it expects to publicly report its top line data from its continuing Phase 3 study of Onivyde in first line pancreatic ductal adenocarcinoma before the end of 2022.

About Merrimack

Merrimack Pharmaceuticals, Inc. is a biopharmaceutical company based in Cambridge, Massachusetts that is entitled to receive up to $450.0 million in contingent milestone payments related to its sale of Onivyde to Ipsen S.A. in April 2017. These milestone payments would be payable by Ipsen upon approval by the U.S. Food and Drug Administration ("FDA") of Onivyde for certain additional clinical indications. Onivyde is already approved by the FDA in combination with fluorouracil (5-FU) and leucovorin (LV) for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. This existing approval is unrelated to any future potential milestone payments. Merrimack's agreement with Ipsen does not require Ipsen to provide Merrimack with any information on the progress of Onivyde clinical trials that is not publicly available. Merrimack is also entitled to receive up to $54.5 million in contingent milestone payments related to its sale of anti-HER3 programs to Elevation Oncology (formerly 14ner Oncology, Inc.) in July 2019.

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, future revenues 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" and similar expressions.
In this press release, Merrimack's forward-looking statements include, among others, Merrimack's rights to receive payments related to certain milestone events or whether such milestones will be achieved, if at all, the sufficiency of Merrimack's cash resources and Merrimack's strategic plan, including any potential distribution of additional cash. Such forward-looking statements involve substantial risks and uncertainties that could cause Merrimack's 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: Positive information about pre-clinical and early stage clinical trial results does not ensure that later stage or larger scale clinical trials will be successful. For example, Onivyde® may not demonstrate promising therapeutic effect or appropriate safety profiles in current or later stage or larger scale clinical trials as a result of known or as yet unanticipated side effects. The results achieved in later stage trials may not be sufficient to meet applicable regulatory standards or to justify further development. Problems or delays may arise prior to the initiation of planned clinical trials, during clinical trials or in the course of developing, testing or manufacturing that could lead Ipsen and Elevation Oncology and their partners and collaborators to fail to initiate or to discontinue development. Even if later stage clinical trials are successful, unexpected concerns may arise from subsequent analysis of data or from additional data. Obstacles may arise or issues may be identified in connection with review of clinical data with regulatory authorities. Regulatory authorities may disagree with Ipsen and Elevation Oncology's view of the data or require additional data or information or additional studies. In addition, the planned timing of initiation and completion of clinical trials based upon Onivyde and the anti-HER Program are subject to the ability of each of Ipsen and Elevation Oncology, respectively, to enroll patients, enter into agreements with clinical trial sites and investigators, and overcome technical hurdles and other issues related to the conduct of the trials for which each of them is responsible. Additionally, each of Ipsen and Elevation Oncology are subject to the risk that they may not successfully commercialize these development programs. Merrimack is also subject to the risk that it may not have funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements. In addition, press releases and other public statements by Ipsen and Elevation Oncology may contain forward-looking statements. 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 SEC on March 9, 2022, any subsequent quarterly report on Form 10-Q filed by Merrimack and the other reports Merrimack files with the Securities and Exchange Commission.

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