

Millendo Therapeutics, Inc. Logo

Millendo Therapeutics Provides Pipeline and Business Update

January 5, 2021

– Further investment in MLE-301, a selective neurokinin 3 receptor (NK3R) antagonist, not planned following initial review of data from Phase 1 clinical study –

– Company exploring expanded range of strategic alternatives to maximize its assets –

ANN ARBOR, Mich.--(BUSINESS WIRE)--Jan. 5, 2021-- [Millendo Therapeutics, Inc.](#) (Nasdaq: MLND), announced today that its Board of Directors has decided to discontinue further investment in MLE-301, a selective neurokinin 3 receptor (NK3R) antagonist for the treatment of menopausal vasomotor symptoms (VMS), based on an analysis of the pharmacokinetic and pharmacodynamic data from the ongoing single ascending dose portion of the Phase 1 study being conducted in healthy male volunteers. While MLE-301 was generally well-tolerated, the data do not support moving forward with its development in the target population of peri- and post-menopausal women, especially with the evolving dynamics of a highly competitive NK3R antagonist market.

Given the Company's limited expected financing options, Millendo's Board of Directors has determined that it is in the best interests of the Company's shareholders to explore an expanded range of strategic alternatives that include, but are not limited to, the potential sale or merger of the Company or its assets. Millendo will continue working with SVB Leerink to assist in its ongoing strategic process.

Carol Gallagher, Chairman of the Board, commented, "We would like to acknowledge and thank all of our employees for their hard work in supporting Millendo's mission of pursuing novel therapies to alleviate patient suffering due to endocrine diseases. The Board has continued to support the Company's ongoing plans and execution efforts; however, at this time the Board believes that it is in the best interest of the Company and its shareholders to actively seek a broad range of strategic alternatives, including a sale or merger of the Company in order to maximize shareholder value."

To conserve cash, Millendo intends to review its operating costs and may plan for a reduction in its workforce in order to focus its resources on essential business activities.

No assurance can be given regarding the outcome or timing of the strategic review process. Millendo does not intend to discuss or disclose further developments regarding the strategic review process unless and until its Board of Directors has approved a specific action or otherwise determined that further disclosure is appropriate or required by law.

About MLE-301

MLE-301 is a neurokinin 3 receptor (NK3R) antagonist that Millendo was developing as a potential treatment of VMS, commonly known as hot flashes and night sweats, in menopausal women. NK3R plays a key role in regulating the activity of KNDy (kisspeptin/NKB/dynorphin) neurons, which has been shown to participate in the generation of VMS.

About Millendo Therapeutics, Inc.

Millendo Therapeutics is a clinical-stage biopharmaceutical company primarily focused on developing novel treatments for endocrine diseases where current therapies do not exist or are insufficient. Millendo seeks to create distinct and transformative treatments where there is a significant unmet medical need. For more information, please visit www.millendo.com.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this press release regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These include statements with respect to the company's plan to cease investing in MLE-301 and its ongoing strategic review process, and, therefore, you are cautioned not to place undue reliance on them. Such forward-looking statements are based on Millendo's expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including that Millendo has incurred significant losses since inception, Millendo has a limited operating history and has never generated any revenue from product sales, Millendo will require additional capital to finance its operations, Millendo's future success is dependent on the successful clinical development, regulatory approval and subsequent commercialization of current and any future product candidates, preclinical studies or earlier clinical trials are not necessarily predictive of future results and the results of Millendo's clinical trials may not support Millendo's product candidate claims, Millendo may encounter substantial delays in its clinical trials or Millendo may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside Millendo's control, Millendo's product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, or limit their commercial potential, Millendo faces substantial competition and Millendo's business, preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic. You should refer to the risk factor disclosure set forth in the periodic reports and other documents Millendo files with the Securities and Exchange Commission available at www.sec.gov, including without limitation Millendo's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2020.

New factors emerge from time to time and it is not possible for Millendo to predict all such factors, nor can Millendo assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements included in this press release are based on information available to Millendo as of the date of this press release. Millendo disclaims any obligation to update such forward-looking statements to reflect events or circumstances after the date of this press release, except as required by applicable law.

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