Millendo Therapeutics, Inc. Logo

Millendo Therapeutics Provides Corporate and Pipeline Update

June 23, 2020

– MLE-301, a selective neurokinin 3 receptor (NK3R) antagonist, advancing with first-in-human trials expected to initiate in 3Q20 –

– Further investment in nevanimibe for congenital adrenal hyperplasia (CAH) not planned following interim data review –

– Strategic evaluation in place to determine future corporate strategy –

ANN ARBOR, Mich.--(BUSINESS WIRE)--Jun. 23, 2020-- Millendo Therapeutics, Inc. (Nasdaq: MLND), a biopharmaceutical company primarily focused on developing novel treatments for endocrine diseases with significant unmet needs, announced today that it has taken steps forward in its evaluation of strategic options to determine the company's future direction. As part of these efforts, Millendo has engaged SVB Leerink to support the strategic review process. The company finished Q1 2020 with $58.9 million in cash, cash equivalents and restricted cash.

"Our board of directors and leadership team recognize the importance of conducting a comprehensive and strategic review. We are aligned in our focus on evaluating our pipeline and its potential, beginning with the advancement of MLE-301," said Julia C. Owens, President and Chief Executive Officer of Millendo Therapeutics. "Our objective is to come away from this process with an actionable plan that leverages our assets, capital and capabilities in a way that maximizes shareholder value."

MLE-301, a selective neurokinin 3 receptor (NK3R) antagonist, continues to advance to first-in-human trials: An IND has been filed to study MLE-301 for the treatment of vasomotor symptoms (VMS), also known as hot flashes and night sweats, in menopausal women. VMS currently impact 70% of peri/post-menopausal women, representing over 20 million women in the US. Phase 1 clinical studies are expected to initiate in 3Q20.

Interim review of nevanimibe open-label Phase 2b study in CAH completed: Results from 10 subjects, nine from cohort 1 and one from cohort 2, with at least 12 weeks of treatment with nevanimibe in this open-label, continuous dose escalation study showed that one patient (10%) met the primary endpoint of achieving 17-hydroxyprogesterone (17-OHP) levels less than or equal to 2-times the upper limit of normal (ULN). Treatment under the amended protocol with dose titration starting at 500 mg BID improved tolerability of nevanimibe. However, based on the observed level of nevanimibe activity and the changing competitive environment, no further investment in the program is currently planned.

About MLE-301

MLE-301 is a neurokinin 3 receptor (NK3R) antagonist that is being developed as a potential treatment of vasomotor symptoms (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 are believed to participate in the generation of VMS. By inhibiting the NK3R signaling on the KNDy neurons and potentially other NK3R-expressing neurons that propagate heat dissipation signals through the hypothalamus, MLE-301 aims to reduce the effects of hyperactive KNDy neurons and thereby address vasomotor symptoms.

About Nevanimibe

Nevanimibe decreases adrenal steroidogenesis through the inhibition of acyl coenzyme A: cholesterol acyltransferase 1, or ACAT1, and is being studied for the treatment of classic congenital adrenal hyperplasia (CAH). CAH is a rare, monogenic adrenal disease that requires lifelong treatment with exogenous cortisol, often at high doses. These chronic high doses of cortisol can result in side effects that include diabetes, obesity, hypertension and psychological problems. An interim review of data from the Phase 2b trial of nevanimibe in CAH (NCT03669549) was conducted; results from 10 subjects with at least 12 weeks of treatment with nevanimibe in the open-label, continuous dose escalation study showed that one patient (10%) met the primary endpoint of achieving 17-hydroxyprogesterone (17-OHP) levels less than or equal to 2-times the upper limit of normal (ULN).

About Millendo Therapeutics, Inc.

Millendo Therapeutics is a 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. The company is currently advancing MLE-301 for the treatment of vasomotor symptoms associated with menopause. 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 Millendo's strategic review and results thereof, Millendo's financial condition, Millendo's future capital needs, the impact of Millendo's plan to not further invest in the nevanimibe program, Millendo's timeline for the continued development of MLE-301 for menopausal vasomotor symptoms, 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 March 31, 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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