Millendo Therapeutics, Inc. Logo

Millendo Therapeutics Reports Second Quarter 2020 Operating and Financial Results

August 10, 2020

– Phase 1 clinical trial to initiate in 3Q20 for MLE-301, a selective NK3R antagonist being studied for the treatment of vasomotor symptoms (VMS) in menopausal women –

ANN ARBOR, Mich.--(BUSINESS WIRE)--Aug. 10, 2020-- Millendo Therapeutics, Inc. (Nasdaq: MLND), a clinical-stage biopharmaceutical company primarily focused on developing novel treatments for endocrine diseases with significant unmet needs, today provided a corporate update and reported financial results for the quarter ended June 30, 2020.

"We are preparing for the initiation of the Phase 1 clinical trial of MLE-301, which has the potential to be a non-hormonal treatment option for the millions of women who experience vasomotor symptoms associated with menopause," said Julia C. Owens, President and Chief Executive Officer of Millendo Therapeutics. "In addition, we are continuing to evaluate our strategic options to advance our commitment to developing and commercializing therapeutics for patients suffering from diseases with significant burden and high unmet need."

Second Quarter 2020 and Recent Highlights

- **MLE-301 Phase 1 clinical trials to be initiated in 3Q20 as planned**: A selective neurokinin 3 receptor (NK3R) antagonist, MLE-301 is being developed for the treatment of vasomotor symptoms (VMS), commonly known as hot flashes and night sweats, in menopausal women. With the well-established role of NK3R in VMS, MLE-301 may have meaningful potential in an area of high unmet medical need. The company continues to monitor the COVID-19 pandemic closely and will provide updates pending any potential impact to trial enrollment.
- **Further investment in nevanimibe for congenital adrenal hyperplasia (CAH) not planned following an interim data review**: Results from 10 subjects, nine from cohort 1 and one from cohort 2, with at least 12 weeks of treatment with nevanimibe in the open-label Phase 2b study were announced on June 23, 2020, and 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. 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, as previously disclosed.
- **Discontinuation of the livoletide program in Prader-Willi syndrome (PWS):** Topline data from the Phase 2b ZEPHYR study of livoletide in PWS were announced on April 6, 2020, and showed that treatment with livoletide did not result in a statistically significant improvement in hyperphagia and food-related behaviors compared to placebo, as measured by the Hyperphagia Questionnaire for Clinical Trials. As a result, the company discontinued the program and implemented staffing reductions.
- **Comprehensive evaluation of strategic options continues**: Millendo has engaged SVB Leerink to support a strategic review process which is intended to result in an actionable plan that leverages the company's assets, capital and capabilities to maximize shareholder value.

Second Quarter 2020 Financial Results

Cash Position: Cash, cash equivalents and restricted cash were $51.0 million at June 30, 2020, compared to $63.5 million at December 31, 2019.

Research and Development (R&D) Expenses: R&D expenses were $6.5 million for the second quarter 2020, as compared to $6.0 million for the same period in 2019. The increase in R&D expenses was primarily driven by increased spending on MLE-301, for which we expect to initiate the Phase 1 clinical trial in the third quarter 2020.

General and Administrative (G&A) Expenses: G&A expenses were $4.1 million for the second quarter 2020, as compared to $4.2 million for the same period in 2019. The decrease in G&A expenses was primarily driven by decreased professional fees as a result of lower legal and consulting fees incurred as compared to the prior period. These decreases were partially offset by increases in compensation and stock-based compensation expense as a result of an increase in our general and administrative headcount and changes to compensation arrangements and an increase in insurance and rent and facility-related expenses.

Net Loss: The company's net loss for the quarter ended June 30, 2020 was $10.7 million as compared to $9.9 million for the same period in 2019.

2020 Financial Guidance

Millendo expects that its cash, cash equivalents and restricted cash will support the company's current development and operational plans into 2022.

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 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, 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 June 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.

Millendo Therapeutics, Inc.
Condensed Statements of Operations
(Unaudited)
(in thousands except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating Expenses				
Research and development	$ 6,466	$ 5,981	$ 14,006	$ 12,185
General and administrative	4,138	4,179	8,733	8,632
Loss from operations	10,604	10,160	22,739	20,817
Other expense (income), net	68	(289)	(69)	(580)
Net loss	$ (10,672)	$ (9,871)	$ (22,670)	$ (20,237)
Net loss per share of common stock, basic and diluted	$ (0.56)	$ (0.74)	$ (1.21)	$ (1.51)
Weighted-average shares of common stock outstanding, basic and diluted	18,999,223	13,379,842	18,723,865	13,368,981

Millendo Therapeutics, Inc.
Condensed Balance Sheet Data
(Unaudited)
(in thousands)

	June 30, 2020	December 31, 2019
Cash, cash equivalents and restricted cash	$ 51,017	$ 63,512
Other assets	6,115	11,458
Total assets	$ 57,132	$ 74,970
Total liabilities	$ 12,188	$ 15,099
Total stockholders' equity	44,944	59,871
Total liabilities and stockholders' equity	$ 57,132	$ 74,970

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