Millendo Therapeutics Reports First Quarter 2019 Operating and Financial Results

– Initiated pivotal study of livoletide in Prader-Willi syndrome (PWS) –

– Established foundation for a commercial organization in Boston –

– Protocol amendment underway for nevanimibe study in congenital adrenal hyperplasia (CAH) –

ANN ARBOR, Mich., May 15, 2019 – Millendo Therapeutics, Inc. (Nasdaq: MLND), a clinical-stage biopharmaceutical company developing novel treatments for orphan endocrine diseases, today provided a corporate update and reported financial results for the first quarter 2019 ended March 31, 2019.

"Our first quarter accomplishments represent important progress toward the achievement of our strategic priorities for 2019, including the initiation of our ZEPHYR pivotal Phase 2b/3 clinical trial in PWS patients, which has the potential to support an NDA submission for livoletide," said Julia C. Owens, President and Chief Executive Officer of Millendo Therapeutics. "Furthermore, we presented on both trials for our late stage clinical candidates, livoletide and nevanimibe, at ENDO and established the foundation for a commercial organization in the Boston area, ahead of topline data for livoletide in the first half of next year. We look forward to continuing to make important strides for patients, families and caregivers throughout 2019."

First Quarter 2019 and Recent Highlights

- **Initiated ZEPHYR, a Pivotal Phase 2b/3 Clinical Trial of Livoletide in PWS Patients:** In March 2019, Millendo initiated the ZEPHYR trial, which has the potential to support a New Drug Application (NDA) submission. Topline data from the Phase 2b portion of the study is expected in 1H20.
- **Initiated Development of a Pen Delivery System for Livoletide:** Millendo has initiated pre-clinical activities in support of the development of a multi-dose pen device to improve patient and caregiver convenience and further simplify administration of livoletide.

- **Protocol Amendment for Nevanimibe Phase 2b Study in CAH Underway:** Preliminary data with a starting dose of 1000 mg BID showed lower tolerability than expected based on prior clinical experience with the drug. Enrollment will be paused while a protocol amendment is submitted to add a lower starting dose. Patients currently enrolled in the study will continue per protocol and may dose escalate as planned.
- **Delivered Multiple Presentations at ENDO 2019:** In March, Millendo presented three posters at ENDO 2019, including an overview of the study design for ZEPHYR, data from the livoletide nonclinical safety program, and an overview of the ongoing nevanimibe Phase 2b study in CAH.
- **Initiated Building a Commercial Organization in the Boston area:** In April, Millendo entered into a lease for offices in Lexington, MA, and has begun to establish a commercial organization to help prepare for potential future product launch.

First Quarter 2019 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were $67.0 million at March 31, 2019, compared to $77.7 million at December 31, 2018.

Research and Development (R&D) Expenses: R&D expenses were $6.2 million for the first quarter 2019, as compared to $2.8 million for the same period in 2018. The increase in R&D expenses was primarily driven by increased spending on the company's Phase 2b/3 pivotal study of livoletide in PWS and higher employee compensation costs due to increased headcount.

General and Administrative (G&A) Expenses: G&A expenses were $4.5 million for the first quarter 2019, as compared to $1.6 million for the same period in 2018. The increase in G&A expenses was primarily driven by increased costs related to employee compensation and professional fees to support ongoing business operations and compliance with obligations associated with being a publicly traded company.

Net Loss: The company's net loss for the quarter ended March 31, 2019 was $10.4 million as compared to $4.4 million for the same period in 2018.

2019 Financial Guidance

Millendo expects that its cash, cash equivalents, and marketable securities will support the company's capital needs into the second half of 2020, beyond the readout for the topline results of the Phase 2b portion of the Phase 2b/3 pivotal study of livoletide in PWS, which is expected in the first half of 2020. This cash runway guidance is based on the company's current operational plans and excludes any additional funding or business development activities.

About Livoletide

Millendo's lead asset, livoletide, is an unacylated ghrelin analogue in late stage clinical development for the treatment of Prader-Willi syndrome (PWS), a rare genetic disease characterized by hyperphagia, a chronic unrelenting hunger, that leads to obesity, metabolic dysfunction, reduced quality of life and early mortality. In March 2019, the company initiated a pivotal Phase 2b/3 clinical study of livoletide in patients with PWS. In a previous randomized, double-blind, placebo-controlled Phase 2 clinical trial in 47 patients with PWS, administration of livoletide once daily was associated with a clinically meaningful improvement in hyperphagia, as well as a reduction in appetite. Millendo has received orphan drug designation for livoletide from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of PWS. For more information about Millendo's pivotal study of livoletide (ZEPHYR) please visit www.clinicaltrials.gov (NCT03790865) or the Patients and Families portion of our website.

About Nevanimibe

Nevanimibe decreases adrenal steroidogenesis through the inhibition of ACAT1 and is being studied for the treatment of two orphan adrenal diseases: classic congenital adrenal hyperplasia (CAH) and endogenous Cushing's syndrome (CS). CAH is a rare, monogenic adrenal disease that requires lifelong treatment with exogenous cortisol, often at high doses, which can make it difficult for physicians to appropriately treat CAH without causing adverse consequences. Millendo has received orphan drug designation for nevanimibe for the treatment of CAH and CS from the FDA, as well as from the EMA for the treatment of CAH. In a Phase 2 proof-of-concept clinical trial in patients with CAH, Millendo observed nevanimibe to be associated with clear signs of clinical activity in seven of 10 treated patients. A Phase 2b trial of nevanimibe in CAH (NCT03669549) is active with enrollment currently paused as described above, and a Phase 2 trial of nevanimibe in CS (NCT03053271) is ongoing.

About Millendo Therapeutics, Inc.

Millendo Therapeutics is a late-stage biopharmaceutical company focused on developing novel treatments for orphan endocrine diseases where current therapies do not exist or are insufficient. As a leading orphan endocrine company, Millendo creates distinct and transformative treatments where there is a significant unmet medical need. The company is currently advancing livoletide for the treatment of Prader-Willi syndrome and nevanimibe for the treatment of classic congenital adrenal hyperplasia and endogenous Cushing's syndrome. 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. These include statements regarding Millendo's expectations regarding the potential for an NDA submission for livoletide, the timing of data from its clinical trials, including the timing of topline data from the Phase 2b portion of its ZEPHYR trial, the potential of a future product launch, Millendo's expectations regarding its 2019 and 2020 milestones, and Millendo's expectations regarding its cash runway, and, therefore, you are cautioned not to place undue reliance on them. 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. 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 livoletide, nevanimibe 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 livoletide or nevanimibe 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 and Millendo faces substantial competition. You should refer to the risk factor disclosure set forth in the periodic reports and other documents we file with the SEC available at www.sec.gov, including without limitation our Annual Report on Form 10-K for our fiscal year ended December 31, 2018 and our Quarterly Report on Form 10-Q for our fiscal quarter ended March 31, 2019.

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

(in thousands except share and per share amounts)

	Three Months Ended March 31,	
	2019	**2018**
Operating Expenses		
Research and development	$ 6,204	$ 2,769
General and administrative	4,453	1,619
Loss from operations	10,657	4,388
Other (income) expense, net	(291)	(2)
Net loss	(10,366)	(4,386)
Net loss attributable to noncontrolling interest	-	125
Net loss attributable to common stockholders	$ (10,366)	$ (4,261)
Net loss per share of common stock, basic and diluted	$ (0.78)	$ (6.00)
Weighted-average shares of common stock outstanding, basic and diluted	13,357,999	710,390

Millendo Therapeutics, Inc.

Condensed Balance Sheet Data

(in thousands)

	March 31, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 66,987	$ 77,671
Other assets	7,318	6,403
Total assets	$ 74,305	$ 84,074
Total liabilities	$ 10,619	$ 10,952
Total stockholders' equity	63,686	73,122
Total liabilities and stockholders' equity	$ 74,305	$ 84,074

Millendo Investor Contact:
Stephanie Ascher
Stern Investor Relations
212-362-1200
stephanie.ascher@sternir.com

Millendo Media Contact:
Betsy Yates
MacDougall
781-235-3094
byates@macbiocom.com

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