Millendo Reports Full Year 2018 Operating and Financial Results

--Initiated ZEPHYR, a pivotal Phase 2b/3 clinical study of livoletide for patients with Prader-Willi syndrome (PWS), in 1Q19--

--Topline data from Phase 2b Portion of ZEPHYR and Phase 2b clinical study of nevanimibe for classic congenital adrenal hyperplasia (CAH) expected in 1H20--

--Completed successful merger and associated financing resulting in $85M in total proceeds and sufficient cash runway to support late-stage clinical development--

ANN ARBOR, Mich., March 29, 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 year ended December 31, 2018.

“2018 was a transformative year for Millendo, as we continued to advance our leading orphan endocrine pipeline, prepared for the initiation of a pivotal Phase 2b/3 trial of livoletide for PWS, advanced nevanimibe into a Phase 2b trial in CAH and became a publicly traded company,” said Julia C. Owens, President and Chief Executive Officer of Millendo Therapeutics. “Our focus in 2019 is to advance our first-in-class programs for livoletide and nevanimibe and establish our commercial capabilities to support our late-stage pipeline assets. In addition, we expect to report topline data from our PWS and CAH clinical trials in the first half of 2020.”

Fourth Quarter 2018 and Recent Highlights

- **Initiated ZEPHYR, a Pivotal Phase 2b/3 Clinical Study of Livoletide:** In March 2019, Millendo initiated ZEPHYR, one of the largest global PWS studies ever conducted. The company expects to recruit 150 patients from up to 40 clinical sites across the United States and Europe in the Phase 2b portion of the pivotal study, which has the potential to support a New Drug Application (NDA) submission.
- **Initiated Phase 2b Clinical Study of Nevanimibe in Patients with CAH:** In September 2018, Millendo initiated a Phase 2b clinical trial of nevanimibe in patients

with CAH. This trial was designed based on the Phase 2 dose-escalation trial that established proof-of-concept for nevanimibe, and is expected to include 20-24 patients across approximately 10 sites.

- **Became a Publicly-Traded Company:** In December 2018, Millendo completed a successful merger and associated financing resulting in total proceeds of $85 million, which will be used to fund the company's late-stage programs in orphan endocrine diseases into the second half of 2020.
- **Strengthened Executive Leadership Team:** In 2018, Millendo appointed Louis Arcudi III as Chief Financial Officer and Ryan Zeidan, Ph.D., as Senior Vice President, Development.

Anticipated 2019-2020 Milestones

- Establish a commercial organization in the Boston area in the second quarter of 2019.
- Report topline data from the Phase 2b study of nevanimibe in patients with CAH in the first half of 2020, following a study update in the second half of 2019.
- Report topline data from the Phase 2b study of livoletide in patients with PWS in the first half of 2020.

Full Year 2018 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were $77.7 million at December 31, 2018, compared to $17.6 million at December 31, 2017.

Research and Development (R&D) Expenses: R&D expenses were $14.4 million for 2018, as compared to $14.5 million for the same period in 2017. The decrease in R&D expenses was primarily driven by a pipeline change towards support of the company's Phase 2 clinical studies in livoletide and nevanimibe, offset by higher employee compensation costs due to increased headcount.

General and Administrative (G&A) Expenses: G&A expenses were $8.7 million for 2018, as compared to $6.0 million for the same period in 2017. 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 year ended December 31, 2018 was $27.2 million.

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 clinical study of nevanimibe in CAH and the Phase 2b portion of the Phase 2b/3 pivotal study of livoletide in PWS, which are both 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 that may be received or business development activities that may be undertaken.

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, a pivotal Phase 2b/3 clinical study of livoletide in patients with PWS was initiated. In a 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, or FDA, and the European Medicines Agency, or EMA, for the treatment of PWS. For more information about Millendo Therapeutics' pivotal study of livoletide (ZEPHYR) please visit www.clinicaltrials.gov (NCT03790865).

About Nevanimibe

Nevanimibe decreases adrenal steroidogenesis through the selective 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, Millendo observed nevanimibe to be associated with clear signs of clinical activity in seven of 10 treated patients and was reported to be well tolerated at all dose levels. Millendo initiated a Phase 2b trial of nevanimibe in CAH in September 2018 (NCT03669549). A Phase 2 trial of nevanimibe for the treatment of patients with CS is ongoing (NCT03053271).

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 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, known as the PSLRA. These include statements regarding Millendo's expectation regarding the timing of data from its clinical trials, 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. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Millendo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. Millendo uses words such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA. 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. These risks and uncertainties are more fully described in Millendo's filings with the Securities and Exchange Commission (the "SEC"), including in the section entitled "Risks Related to Millendo" in OvaScience, Inc.'s (with whom Millendo merged as described above) Form S-4 as filed on September 26, 2018 with the SEC, and subsequent reports that Millendo files with the SEC.

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)

	Year Ended December 31,	
	2018	**2017**
Operating Expenses		
Research and development	$ 14,425	$ 14,526
Acquired in-process research and development	-	63,844
General and administrative	8,691	5,956
Other general expenses	3,758	-
Loss from operations	26,874	84,326
Other (income) expense, net	303	260
Net loss	(27,177)	(84,586)
Net (income) loss attributable to noncontrolling interest	(15)	8
Net loss attributable to common stockholders	$ (27,192)	$ (84,578)
Net loss per share of common stock, basic and diluted	$ (17.58)	$ (321.81)
Weighted-average shares of common stock outstanding, basic and diluted	1,547,051	262,823

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

	December 31,	
	2018	**2017**
Cash, cash equivalents and marketable securities	$ 77,671	$ 17,578
Other assets	6,403	2,234
Total assets	$ 84,074	$ 19,812
Total liabilities	$ 10,952	$ 4,829
Convertible preferred stock	-	132,922
Redeemable noncontrolling interests	-	10,584
Total stockholders' equity (deficit)	73,122	(128,523)
Total liabilities, convertible preferred stock, redeemable noncontrolling interests and stockholders' equity (deficit)	$ 84,074	$ 19,812

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