Millendo Therapeutics Announces 21st European Congress of Endocrinology 2019 Presentations on Livoletide for Prader-Willi Syndrome and Nevanimibe for Classic Congenital Adrenal Hyperplasia

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ANN ARBOR, Mich.--(BUSINESS WIRE)--May 8, 2019-- Millendo Therapeutics, Inc. (Nasdaq: MLND), a clinical-stage biopharmaceutical company developing novel treatments for orphan endocrine diseases, announced today that its late-stage clinical candidates, livoletide and nevanimibe, will be featured in three concurrent poster presentations at the European Society of Endocrinology's 21 stEuropean Congress of Endocrinology (ECE), taking place May 18-21, 2019 in Lyon, France.

Livoletide, a potential first-in-class treatment for Prader-Willi syndrome (PWS), will be featured in two poster presentations. The company will provide an overview of the pivotal Phase 2b/3 ZEPHYR clinical trial, initiated in March 2019, to evaluate the safety and efficacy of livoletide for hyperphagia and food-related behaviors in PWS patients in one poster. Data from the livoletide nonclinical safety program to support its clinical development will be presented in another poster. The company will also give an overview of its ongoing nevanimibe Phase 2b study in patients with classic congenital adrenal hyperplasia (CAH) in a third poster presentation. Top-line results from the Phase 2b portion of ZEPHYR and the Phase 2b study for nevanimibe in CAH are expected in the first half of 2020.

Details of the poster presentations are as follows, and will take place at the ECE on Monday, May 20 from 1:00 – 3:00 PM:

Title: Trial-in-Progress: ZEPHYR, a Pivotal Phase 2b/3 Randomized, Placebo-Controlled Study of Livoletide, a Novel Unacylated Ghrelin Analogue, for the Treatment of Hyperphagia and Food-Related Behaviors in Patients with Prader-Willi Syndrome
Location: Exhibition Hall, P619

Title: Nonclinical Development of Livoletide (AZP-531), a Peptide Analogue of Unacylated Ghrelin for the Treatment of Hyperphagia in Prader-Willi Syndrome
Location: Exhibition Hall, P621

Title: Trial-in-Progress: A Multicenter, Dose-Titration, Open-Label Phase 2b Study of Nevanimibe Hydrochloride, a Novel ACAT1 Inhibitor, for the Treatment of Classic Congenital Adrenal Hyperplasia
Location: Exhibition Hall, P730

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, 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 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 statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements in this press release represent our views as of the date of this press release. We anticipate that

subsequent events and developments may cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release. 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.

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