



Millendo Therapeutics Announces ENDO 2019 Presentations on Livoletide for Prader-Willi Syndrome and Nevanimibe for Classic Congenital Adrenal Hyperplasia

March 14, 2019

ANN ARBOR, Mich.--(BUSINESS WIRE)--Mar. 14, 2019-- [Millendo Therapeutics, Inc.](#) (Nasdaq: MLND), a clinical-stage biopharmaceutical company developing novel treatments for orphan endocrine diseases, announced today that its clinical candidates, livoletide (AZP-531) and nevanimibe (ATR-101), will be featured in three poster presentations at ENDO 2019, taking place March 23-26, 2019 in New Orleans, La.

Livoletide, a potential first-in-class treatment for Prader-Willi syndrome (PWS), will be featured in two poster sessions. The company will provide an overview of the study design for the pivotal Phase 2b/3 ZEPHYR clinical trial to evaluate the safety and efficacy of livoletide for hyperphagia and related food-related behaviors in PWS patients in one poster session. Data from the livoletide nonclinical safety program to support its clinical development will be presented in another session. The company will also give an overview of its ongoing nevanimibe Phase 2b open-label study in patients with classic congenital adrenal hyperplasia (CAH) in a third session. 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:

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

Session: P05, Obesity Comorbidities and Therapies

Date/ Time: Saturday, March 23, 2019, 1:00 – 3:00 PM CST

Location: ENDOExpo

Abstract: <https://www.abstractsonline.com/pp8/#!/5752/presentation/18359>

Title: Multicenter, Dose-titration, Open-Label Phase 2b Study of Nevanimibe Hydrochloride, a Novel ACAT1 Inhibitor, for the Treatment of Classic Congenital Adrenal Hyperplasia

Session: P37, Adrenal Tumors and Hyperplasia

Date/ Time: Sunday, March 24, 2019, 1:00 – 3:00 PM CST

Location: ENDOExpo

Abstract: <https://www.abstractsonline.com/pp8/#!/5752/presentation/19302>

Title: Nonclinical Development of AZP-531 (Livoletide): A Peptide Analog of Unacylated Ghrelin for the Treatment of Hyperphagia in Prader-Willi Syndrome

Session: P49, Treatment of Obesity in Unique Populations

Date/ Time: Monday, March 25, 2019, 1:00 – 3:00 PM CST

Location: ENDOExpo

Abstract: <https://www.abstractsonline.com/pp8/#!/5752/presentation/11380>

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 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 management's intentions, plans, beliefs, expectations or forecasts for the future, 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 the timing of the availability of data from Millendo's clinical trials.

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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Source: Millendo Therapeutics, Inc.

Millendo Investor Contact:

Stephanie Ascher
Stern Investor Relations
212-362-1200
stephanie@sternir.com

Millendo Media Contact:

Betsy Yates
MacDougall
912-695-7081
byates@macbiocom.com