Millendo Therapeutics, Inc. Logo

Millendo Therapeutics to Present at Prader-Willi Syndrome Conferences

September 26, 2019

Presentations on livoletide and PWS at the Foundation for Prader-Willi Research Annual Research Symposium and Family Conference and the Prader-Willi Syndrome Association USA National Convention

ANN ARBOR, Mich.--(BUSINESS WIRE)--Sep. 26, 2019-- Millendo Therapeutics, Inc. (Nasdaq: MLND), a clinical-stage biopharmaceutical company developing novel treatments primarily for orphan endocrine diseases, today announced that it will participate in oral presentations and poster sessions at two upcoming Prader-Willi syndrome (PWS) conferences. Presentations will be made by both PWS clinician thought leaders and Millendo scientific personnel, and will feature a trial-in-progress report on Millendo's pivotal Phase 2b/3 clinical trial of livoletide for PWS (ZEPHYR), a comprehensive review of livoletide's preclinical studies up to 9 months in duration, data on livoletide in obese and non-obese populations and concomitant use with growth hormone therapy, and new research insights from claims database analyses on the prevalence of comorbidities and overall outcomes in the PWS population.

"With a data readout from our ZEPHYR trial on the horizon in the first half of next year, we are thrilled to have the opportunity to share new insights on the PWS patient population as well as livoletide, our lead product candidate for the treatment of PWS," said Julia C. Owens, Ph.D., President and Chief Executive Officer of Millendo Therapeutics. "We are honored to partner with FPWR and PWSA and look forward to engaging with the scientific and patient communities at these important PWS conferences."

The Foundation for Prader-Willi Research's (FPWR) Annual Research Symposium and Family Conference integrates education, research and community building to bring together multiple stakeholders impacted by PWS. The conference, October 3-5 in New Orleans, LA, will exhibit noteworthy updates in PWS research and clinical trials and give patient, family and caregiver attendees the opportunity to directly interact with researchers working on PWS.

The 35th Annual Prader-Willi Syndrome Association USA (PWSA) National Convention, October 23-26 in Orlando, FL, serves as a platform for scientists, researchers and medical professionals to collaborate and report on the progress of research to improve the lives of those affected by PWS.

Millendo is a corporate sponsor of both the FPWR and PWSA conferences. Details of the company's presentations at each conference are as follows:

US Prevalence, Mortality, and Comparative Comorbidity Burdens of Patients with Prader-Willi Syndrome: A Population-Level Cohort Study

- **FPWR Annual Research Symposium** – Oral presentation
  Thursday, October 3, 2019, 10:40am-11:00am CDT
  Presenters: Diane E. Stafford, M.D., Stanford Children's Health, Lucile Packard Children's Hospital; Shawn E. McCandless, MD, Children's Hospital of Colorado, University of Colorado Denver School of Medicine

Comparative Comorbidity Burden Among Patients with Prader-Willi Syndrome: A Population-Level Cohort Study

- **FPWR Annual Research Symposium** – Poster presentation
  Thursday, October 3, 2019, 5:00pm-7:00pm CDT
  Presenter: Diane E. Stafford, M.D., Stanford Children's Health, Lucile Packard Children's Hospital

- **PWSA National Convention** – Oral presentation
  Wednesday, October 23, 2019, 3:00pm-3:20pm EDT
  Presenter: Diane E. Stafford, M.D., Stanford Children's Health, Lucile Packard Children's Hospital

US Prevalence & Mortality of Prader-Willi Syndrome: A Population-Based Study of Medical Claims

- **FPWR Annual Research Symposium** – Poster presentation
  Thursday October 3, 2019, 5:00pm-7:00pm CDT
  Presenter: Shawn E. McCandless, M.D., Children's Hospital of Colorado, University of Colorado Denver School of Medicine

- **PWSA National Convention** – Oral presentation
  Wednesday, October 23, 2019, 3:20pm-3:40pm EDT
  Presenter: Shawn E. McCandless, M.D., Children's Hospital of Colorado, University of Colorado Denver School of Medicine

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

- **FPWR Annual Research Symposium** – Oral presentation
  Thursday, October 3, 2019, 4:00pm-4:20pm CDT
  Presenter: Michael Yeh, M.D., M.P.H., Vice President of Medical Affairs, Millendo Therapeutics

- **PWSA National Convention** – Oral presentation
  Thursday, October 24, 2019, 3:20pm-3:40pm EDT
  Presenter: Vivian Lin, M.D., Vice President of Clinical Development, Millendo Therapeutics

Livoletide (AZP-531), an Unacylated Ghrelin Analogue, Improves Hyperphagia and Food-Related Behaviors Both in Obese and Non-Obese People with Prader-Willi Syndrome

- **FPWR Annual Research Symposium** – Poster presentation
  Thursday, October 3, 2019, 5:00pm-7:00pm CDT
  Presenter: Michael Yeh, M.D., M.P.H., Vice President of Medical Affairs, Millendo Therapeutics

- **PWSA National Convention** – Oral presentation
  Thursday, October 24, 2019, 3:40pm-4:00pm EDT
  Presenter: Rania Harisseh, Ph.D., Drug Development Project Coordinator, Millendo Therapeutics

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

- **FPWR Annual Research Symposium** – Poster presentation

Thursday, October 3, 2019, 5:00pm-7:00pm CDT
Presenter: Andrew G. Spencer, Ph.D., Senior Vice President, Preclinical Research and Development

- **PWSA National Convention** – Oral presentation
  Wednesday, October 23, 2019 4:00pm-4:20pm EDT
  Presenter: Andrew G. Spencer, Ph.D., Senior Vice President, Preclinical Research and Development

Chronic Treatment with Livoletide (AZP-531) Does Not Affect IGF-1 Plasma Levels: Preclinical and Clinical Results in People with Prader-Willi Syndrome (PWS)

- **FPWR Annual Research Symposium** – Poster presentation
  Thursday, October 3, 2019, 5:00pm-7:00pm CDT
  Presenter: Andrew G. Spencer, Ph.D., Senior Vice President, Preclinical Research and Development

- **PWSA National Convention** – Oral presentation
  Wednesday, October 23, 2019, 4:20pm-4:40pm EDT
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Prader-Willi Syndrome Clinical Trial Panel

- **FPWR Annual Family Conference** – Panel presentation
  Saturday, October 5, 2019, 9:00am-10:30am CDT
  Panelist: Michael Yeh, M.D., M.P.H., Vice President of Medical Affairs, Millendo Therapeutics

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 Prader-Willi Syndrome
Prader-Willi syndrome (PWS) is a genetic disease caused by the lack of expression of several genes on chromosome 15, which leads to intellectual disability, short stature, incomplete sexual development and hyperphagia, among other symptoms. PWS patients are at risk of premature mortality, usually by the age of 30-40, mainly from obesity related conditions such as cardiovascular disease, respiratory distress and from accidents. The incidence of PWS is approximately 1 in 15,000 births. The prevalence of PWS is estimated between 8,000-11,000 patients in the United States and 13,000-18,000 in Europe. Currently, there is no effective or approved treatment for hyperphagia and abnormal eating behaviors associated with PWS. Growth hormone is used for improvement in height, cognition and body composition, but has no effect on appetite and over-eating. The only way to effectively manage hyperphagia, obesity and related complications of PWS is strict control over access to food, creating significant burden for families and caregivers.

About Millendo Therapeutics, Inc.
Millendo Therapeutics is a late-stage biopharmaceutical company primarily 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, nevanimibe for the treatment of classic congenital adrenal hyperplasia and 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. These include statements regarding Millendo's expectations regarding the timing of data from its clinical trials, including the timing of topline data from the Phase 2b portion of its ZEPHYR trial, 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 June 30, 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.

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