Millendo Therapeutics Inc. has announced the discontinuation of the phase 2b ZEPHYR study in the Prader-Willi syndrome community. Millendo and PWSA (USA) are continuing to discuss the details of this new information. We would like to thank our community for your support of this clinical trial and all other trials that will provide insight into the treatment of PWS.

Press release from Millendo Therapeutics

ANN ARBOR, Mich.--(BUSINESS WIRE)--Apr. 6, 2020-- Millendo Therapeutics, Inc. (Nasdaq: MLND), a biopharmaceutical company primarily focused on developing novel treatments for endocrine diseases, announced today that it is discontinuing the development of livoletide as a potential treatment for Prader-Willi syndrome (PWS). The decision to discontinue the PWS program was based on topline data from the pivotal Phase 2b ZEPHYR study which showed that treatment with livoletide did not result in a statistically significant improvement in hyperphagia and food-related behaviors as measured by the Hyperphagia Questionnaire for Clinical Trials (HQ-CT) compared to placebo.

“Unfortunately, treatment with livoletide did not significantly improve hyperphagia and food-related behaviors in our ZEPHYR study. While we are disappointed in these results, I want to recognize our team’s hard work and commitment in executing this robust study that informed the difficult decision to discontinue the livoletide PWS program,” said Julia C. Owens, President and Chief Executive Officer of Millendo Therapeutics. “We are deeply grateful to the patients, caregivers and researchers who made the ZEPHYR study possible. We are committed to understanding the totality of the Phase 2b results and we intend to report the data at a future scientific meeting or publication when they are available.

The ZEPHYR study was a two-part, randomized, double-blind, placebo-controlled pivotal Phase 2b/3 study. The pivotal Phase 2b study included a three-month double-blind,
placebo-controlled period in which patients (N=158) were randomized to either 60 µg/kg or 120 µg/kg of livoletide, or placebo. The Phase 2b data showed improvements from baseline in HQ-CT scores of -4.7 (p = 0.13) and -3.8 (p = 0.45) for the livoletide treated groups (60 µg/kg or 120 µg/kg, respectively) at 12 weeks compared to -2.8 for placebo. The average HQ-CT baseline score was 20.2. No positive trends were observed for any of the secondary endpoints of fat mass, body weight or waist circumference.

Watch the webcast here.