FOR IMMEDIATE RELEASE

Millendo Therapeutics Announces Publication of Positive Phase 2a Data for MLE4901 for the Treatment of Polycystic Ovary Syndrome

ANN ARBOR, Mich., July 27, 2016 – Millendo Therapeutics, Inc., a company developing novel therapies for endocrine diseases caused by hormone dysregulation, today announced the online publication of positive data from a Phase 2a clinical trial of MLE4901, previously known as AZD4901, for the treatment of polycystic ovary syndrome (PCOS). The article titled, "Neurokinin B receptor antagonism decreases luteinizing hormone and testosterone secretion in women with polycystic ovary syndrome: a randomized, double-blind, placebo-controlled trial," was published online in the *Journal of Clinical Endocrinology and Metabolism*.

As reported in the manuscript, results of the Phase 2a trial demonstrated that MLE4901 was well tolerated in patients with PCOS and met its primary endpoint of a change from baseline in serum luteinizing hormone (LH) concentrations at Day 7 of treatment. At the highest dose tested, twice-daily MLE4901 specifically reduced LH pulse frequency and subsequently serum LH and testosterone concentrations at Day 7 compared to placebo. In non-ovulating patients, these reductions were found to persist through the end of the 28-day study. The trial marks the first large clinical study to address PCOS via modulation of the NKB-GnRH pathway.

"The results of this study demonstrate the tremendous potential of MLE4901, a first-in-class, first-in-disease, non-hormonal therapy for the treatment of PCOS, for which there are currently no approved therapies," said Julia C. Owens, Ph.D., President and Chief Executive Officer of Millendo. "We are eager to continue the development of MLE4901 by initiating a Phase 2b clinical trial in patients with PCOS later this year."

The Phase 2a trial (ClinicalTrials.gov identifier NCT01872078) was a randomized, double blind, placebo-controlled, multi-center, international study evaluating the safety and efficacy of three dose regimens of MLE4901 (20 mg once daily, 20 mg twice daily, and 40 mg twice daily) in 65 PCOS patients. The primary efficacy endpoint was the change from baseline of LH levels to Day 7 of treatment, and the endpoint was analyzed using mixed effects models for repeated measures (MMRM). The results were reported on an intent-to-treat basis. The study was sponsored by AstraZeneca, who licensed the compound to Millendo in 2015.

About Polycystic Ovary Syndrome
Polycystic ovary syndrome (PCOS) is the most common endocrine disease in women, and is estimated to affect 8-20% of the female population. PCOS is caused by Gonadotropin Releasing Hormone (GnRH) hyperpulsatility, which leads to increased luteinizing hormone (LH) pulse frequency and downstream hormonal abnormalities including androgen excess. Clinical symptoms include menstrual dysfunction, androgen excess, metabolic syndrome, and infertility. Current treatments are used off-label and directed at managing symptoms. There are no approved therapies for PCOS on the market.

About MLE4901
MLE4901 leverages recent biological insights that elucidated the central regulator of reproductive hormonal signaling, the KNDy (kisspeptin/neurokinin B/dynorphin) neuron. MLE4901 is an antagonist of the Neurokinin 3 receptor (NK3R) which resides on the KNDy neuron and acts to diminish GnRH hyperpulsatility, the central driver of PCOS.

About Millendo Therapeutics, Inc.

Millendo Therapeutics is focused on developing a portfolio of disease-modifying treatments for endocrine diseases caused by hormone dysregulation. Our product candidates seek to improve the quality of life for patients with orphan and specialty diseases with limited or no approved treatment options. Our clinical programs are designed to address:

- Polycystic Ovary Syndrome (PCOS) – the most common endocrine disease in women
- Congenital Adrenal Hyperplasia (CAH) – a recessive genetic defect of cortisol synthesis
- Endogenous Cushing's Syndrome (CS) – a condition resulting from chronic cortisol excess
- Adrenocortical Carcinoma (ACC) – a rare endocrine malignancy of the adrenal cortex

Our experienced team is committed to bringing these first-in-class therapies to market.
www.millendo.com

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Media Contact:
Blair McCarthy Atkinson
MacDougall Biomedical Communications
Main: +1 781 235 3060
Direct: +1 812 454 6257
batkinson@macbiocom.com

Investor Contact:
Stephanie Ascher
Stern Investor Relations
+1 212 362 1200
stephanie@sternir.com