



FOR IMMEDIATE RELEASE

## **Millendo Therapeutics Announces Initiation of Phase 2b Clinical Trial of MLE4901 in Patients with Polycystic Ovary Syndrome**

ANN ARBOR, Mich., Aug. 16, 2016 – [Millendo Therapeutics, Inc.](#), a company developing novel therapies for endocrine diseases caused by hormone dysregulation, today announced the initiation of a Phase 2b clinical trial evaluating the efficacy of novel oral drug candidate MLE4901, a first-in-class, non-hormonal therapy for the treatment of polycystic ovary syndrome (PCOS). There are currently no approved therapies for PCOS, which is the most common endocrine disease in women.

“We believe our lead candidate, MLE4901, addresses a significant unmet medical need, offering a new therapeutic option for PCOS beyond current off-label therapies, which are limited to managing patient symptoms,” said Julia C. Owens, Ph.D., President and Chief Executive Officer of Millendo. “The initiation of this Phase 2b clinical trial marks the continued advancement of MLE4901 and is an important milestone in the progression of our robust clinical portfolio of novel treatment options for endocrine diseases.”

The Phase 2b clinical trial is a double-blind, randomized, parallel-group, placebo-controlled study designed to evaluate the efficacy of MLE4901 in patients with PCOS over a 7-month dosing period. The primary endpoint will assess the impact of MLE4901 in improving menstrual regularity in women with amenorrhea or oligomenorrhea resulting from PCOS. The multicenter, international study will be conducted at sites in the U.S. and U.K. For additional information on this clinical trial, please visit [clinicaltrials.gov](http://clinicaltrials.gov), trial identifier NCT02865915.

The Company recently announced the publication of results from an earlier Phase 2a clinical trial of MLE4901 in patients with PCOS, which met its primary endpoint of a change from baseline in serum luteinizing hormone (LH) concentrations at Day 7 of treatment. The results were published online in the [Journal of Clinical Endocrinology and Metabolism](#).

### **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 are directed at managing symptoms. There are no approved therapies for PCOS on the market.

### **About MLE4901**

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

### **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](http://www.millendo.com)

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