Millendo Therapeutics Announces Publication of Positive Phase 2 Data for MLE4901 for the Treatment of Vasomotor Symptoms

-- Treatment resulted in significant reduction in number and severity of hot flushes --

ANN ARBOR, Mich., April 3, 2017 – Millendo Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on developing novel treatments for endocrine diseases caused by hormone dysregulation, today announced the publication of positive data from a Phase 2 investigator-initiated clinical trial of MLE4901, previously known as AZD4901, for the treatment of menopausal vasomotor symptoms (VMS), which are defined as hot flushes/flashes and night sweats and affect 70% of menopausal women. The article, titled "Neurokinin 3 receptor antagonism as a novel treatment for menopausal hot flushes: a phase 2, randomised, double-blind, placebo-controlled trial," was authored by the study investigators and published online in *The Lancet*. The results of the study will also be presented today in an oral presentation at the annual meeting of The Endocrine Society (ENDO) in Orlando, Florida at 12:30pm EDT in room W414A of the Orange County Convention and Exhibition Center.

As reported in the manuscript, the Phase 2 study met its primary endpoint. Treatment with MLE4901 twice daily significantly reduced the total weekly number of hot flushes during the final week of a 4-week treatment period by 73% compared to a 28% reduction with placebo ($p<0.0001$). Treatment with MLE4901 also significantly reduced weekly hot flush severity, bother, and interference by 41%, 45%, and 58%, respectively, compared to placebo (each $p<0.0001$). MLE4901 was well tolerated, and no serious adverse events occurred. Three participants developed a mild, reversible, asymptomatic transaminase rise with a normal bilirubin after 28 days of treatment with MLE4901.

"The current standards of therapy for VMS, including hormone replacement therapy (HRT), selective serotonin reuptake inhibitors (SSRIs), and over-the-counter treatments, all have tradeoffs between safety and efficacy such as an increased risk of breast and endometrial cancers," said Waljit S. Dhillo, Ph.D., Professor of Endocrinology and Metabolism at Imperial College London and principal investigator of the study. "While larger scale studies of longer duration will be needed, this study has demonstrated the practice-changing capacity of MLE4901 for the treatment of VMS in that it has the potential to treat hot flush symptoms without the need for oestrogen exposure."

"The results of this study provide a strong rationale for the expanded development of MLE4901 into patients with VMS, for which there is a clear need for an effective non-hormonal treatment option," said Julia C. Owens, Ph.D., President and Chief Executive Officer of Millendo. "In addition to the continuation of our Phase 2b clinical program in polycystic ovary syndrome (PCOS), we plan to initiate a Phase 2b clinical trial of MLE4901 in patients with VMS later this year."

The Phase 2 trial (clinicaltrials.gov identifier NCT02668185) was a randomized, double-blind, placebo-controlled, single-center crossover study evaluating the effectiveness of MLE4901 in 28 patients with VMS. Patients received four weeks of twice-daily MLE4901 or placebo followed by a two-week washout period, then four weeks of whichever intervention they did not receive first followed by a two-week monitoring period. The primary outcome measure was the total number of hot flushes during the final week of both treatment periods. The study was carried out at Imperial College London and the research was funded by the Medical Research Council and the National Institute for Health Research (NIHR).

About Vasomotor Symptoms

Vasomotor symptoms (VMS), defined as hot flushes/flashes and night sweats, are experienced by a majority of women during menopause. The sensations of heat and/or perspiration associated with VMS occur randomly, generally last several minutes, and are often preceded or followed by sensations of cold and/or shivering. VMS tend to start in the peri-menopausal period and continue for an average of 7.4

years, but may last for up to 15 years or more. VMS interfere with the lives of affected women in a number of ways, including disrupting the ability to sleep and concentrate and causing anxiety and depression.

Up to 70% of women in menopause will develop VMS, with approximately 20 million women in the United States currently experiencing VMS. Current standards of therapy for VMS include hormone replacement therapy (HRT), selective serotonin reuptake inhibitors (SSRIs), and a variety of over-the-counter treatments. None of these options has both a strong safety and efficacy profile, and there is a clear need for an effective non-hormonal treatment option.

About MLE4901
MLE4901 is an antagonist of the neurokinin 3 receptor (NK3R), which resides on the KNDy (kisspeptin/neurokinin B/dynorphin) neuron. MLE4901 leverages recent biological insights that elucidated the critical role of the KNDy neuron as a regulator of reproductive hormonal signaling. MLE4901 is being developed for the treatment of polycystic ovary syndrome (PCOS), one of the most common hormonal endocrine disorders in women, and vasomotor symptoms (VMS), defined as hot flashes and night sweats, which are experienced by a majority of women during menopause.

About Millendo Therapeutics, Inc.
Millendo Therapeutics is focused on developing novel treatments for endocrine diseases caused by hormone dysregulation. Our mission is to build a leading endocrine company that creates distinct and transformative treatments for a wide range of diseases where there is a significant unmet medical need. We are advancing two product candidates in five indications: MLE4901, designed to address Polycystic Ovary Syndrome (PCOS) and Vasomotor Symptoms (VMS), and ATR-101 for the treatment of Classic Congenital Adrenal Hyperplasia (CAH), Endogenous Cushing's Syndrome (CS), and Adrenocortical Carcinoma (ACC). www.millendo.com

###

Media Contact:
Casey R. Doucette, Ph.D.
MacDougall Biomedical Communications
millendo@macbiocom.com

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