Millendo Therapeutics Announces Data Presentations at Society for Endocrinology British Endocrine Societies Conference

-- Presentations summarize preclinical data supporting MLE4901 and ATR-101 programs --

ANN ARBOR, Mich., Nov. 2, 2016 – Millendo Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on developing novel treatments for endocrine diseases caused by hormone dysregulation, today announced that it will present data from its MLE4901 and ATR-101 programs at the Society for Endocrinology (SfE) British Endocrine Societies (BES) 2016 conference, being held from November 7-9, 2016 in Brighton, United Kingdom.

“Patients with polycystic ovary syndrome (PCOS) experience numerous symptoms, including androgen excess, which results in excessive facial hair and acne. In our preclinical studies, we observed that administration of MLE4901 is associated with reduced testosterone levels, which were sustained throughout treatment, providing support for the development of MLE4901 as a treatment for PCOS,” said Stephen Hunt, Ph.D., Chief Scientific Officer of Millendo. “In separate studies, treatment with ATR-101 in a preclinical model and in canines with naturally-occurring Cushing’s syndrome resulted in reduced ACTH-stimulated cortisol levels. These studies provide support for the clinical development of ATR-101 in patients with endogenous Cushing’s syndrome, in which chronic cortisol excess results in a multitude of symptoms including weight gain, fatigue, hypertension, diabetes, and bone loss.”

“The data presented at SfE BES 2016 support our ongoing Phase 2b clinical trial of MLE4901 in polycystic ovary syndrome and support the rationale for clinical development of ATR-101 in endogenous Cushing’s syndrome,” said Julia C. Owens, Ph.D., President and Chief Executive Officer of Millendo. “Based on these and other studies to date, we believe that MLE4901 and ATR-101 have strong potential as novel therapies for patients with endocrine diseases for which there are limited or no approved treatment options.”

Dr. Hunt will give a podium presentation on preclinical data for MLE4901, currently in Phase 2b clinical trials in patients with polycystic ovary syndrome (PCOS). In addition, Dr. Hunt will present two posters on preclinical data for ATR-101, currently in clinical trials in patients with congenital adrenal hyperplasia and adrenocortical carcinoma. Details of the abstracts are as follows:

Title: MLE4901, a neurokinin 3 receptor antagonist, shows reproductive tract effects and sustained pharmacodynamic activity consistent with HPG suppression after 13 weeks of oral administration in dogs
Session: Oral Communications 2 – Neuroendocrinology and Reproduction
Date: Tuesday, November 8, 2016
Time: 2:30 – 2:45 p.m. GMT
Location: Syndicate 1, Brighton Centre

In a preclinical model, MLE4901 administration resulted in reduced levels of testosterone. These effects were confined to reproductive tissues and were sustained throughout a treatment course of 13 weeks, with pharmacodynamic response remaining intact at day 91 as demonstrated by decreased testosterone levels.

Title: Characterization of adrenal-specific effects of ATR-101, a selective ACAT1 antagonist, in dogs
Session: Poster
Date: Tuesday, November 8, 2016
Time: 1:00 – 2:45 p.m. GMT
Location: Auditorium 1, Exhibition Area, Brighton Centre
In an *in vivo* preclinical model, treatment with the selective acyl-CoA: cholesterol acyltransferase 1 (ACAT1) inhibitor ATR-101 was found to significantly decrease ACTH-stimulated cortisol levels and was safe at high exposures. In a recovery period after three months of dosing, signs of reversal of these adrenal effects were observed.

**Title:** Characterization of clinical, biochemical and adrenal hormonal effects of ATR-101, a selective ACAT1 antagonist, in dogs with naturally-occurring Cushing's syndrome  
**Session:** Poster  
**Date:** Monday, November 7, 2016  
**Time:** 1:00 – 2:45 p.m. GMT  
**Location:** Auditorium 1, Exhibition Area, Brighton Centre

In canines with naturally-occurring Cushing’s syndrome, treatment with ATR-101 demonstrated efficacy in lowering ACTH-stimulated cortisol levels in 9 out of 10 subjects regardless of underlying etiology in both pituitary- and adrenal-dependent disease states.

**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 critical role of the KNDy neuron as a regulator of reproductive hormonal signaling.

**About ATR-101**  
ATR-101, a potent and adrenal-selective inhibitor of ACAT1, seeks to reduce adrenal steroid production at lower doses, and, at higher doses, can induce apoptosis of cells derived from the adrenal cortex. ATR-101 is currently in clinical development for the treatment of classic congenital adrenal hyperplasia (CAH) and adrenocortical carcinoma (ACC), with planned development in endogenous Cushing’s syndrome (CS).

**About Millendo Therapeutics, Inc.**  
Millendo Therapeutics is focused on developing novel treatments for endocrine diseases caused by hormone dysregulation. We are currently advancing two product candidates to treat four diseases. Based on our understanding of the novel biology underlying hormone dysregulation in endocrine diseases, we are developing our product candidates for conditions where current therapies are insufficient. 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

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