

Millendo Therapeutics, Inc. Logo

Millendo Therapeutics Announces Initiation of First-in-Human Clinical Trial of MLE-301, a Selective NK3R Antagonist

September 24, 2020

– First subject dosed with MLE-301, for the treatment of vasomotor symptoms (VMS) in menopausal women –

– Phase 1 study will evaluate safety, pharmacokinetics and preliminary efficacy –

ANN ARBOR, Mich.--(BUSINESS WIRE)--Sep. 24, 2020-- [Millendo Therapeutics, Inc.](#) (Nasdaq: MLND), a clinical-stage biopharmaceutical company primarily focused on developing novel treatments for endocrine diseases with significant unmet needs, announced dosing of the first subject in a Phase 1 clinical trial evaluating the safety, pharmacokinetics and preliminary efficacy of MLE-301, a selective neurokinin 3 receptor (NK3R) antagonist that is being developed for the treatment of VMS, commonly known as hot flashes and night sweats, in menopausal women.

"We are pleased to advance MLE-301 into clinical development, prioritizing our resources on this valuable asset and leveraging Millendo's expertise in the NK3R category," said Julia C. Owens, President and Chief Executive Officer of Millendo Therapeutics. "The company is focused on executing our Phase 1 study and understanding more about the safety, PK/PD and efficacy profile of MLE-301 based on the resulting data from this study."

The first-in-human trial is designed to evaluate the safety and tolerability of MLE-301. The single ascending dose portion of the study will be conducted in healthy male volunteers, to determine the pharmacokinetics of MLE-301 and its pharmacodynamic profile as measured by reductions of biomarkers (luteinizing hormone, testosterone). The Phase 1 multiple ascending dose portion will enroll post-menopausal women, allowing measurement of reductions in VMS frequency and severity, and establishment of initial clinical proof of concept. The Phase 1 clinical trial is supported by strong preclinical data that showed potency and selectivity for the NK3R receptor, the potential for once-daily dosing, and testosterone lowering effects consistent with the expected activity of an NK3R antagonist. Based on its demonstrated *in vitro* and *in vivo* activity, Millendo believes MLE-301 may have meaningful clinical impact in an area of high unmet medical need.

"Over 20 million women in the U.S. suffer from VMS associated with menopause, including hot flashes and night sweats that can severely impact quality of life, overall productivity and long-term healthcare utilization," said Christophe Arbet-Engels, M.D., Ph.D., Chief Medical Officer of Millendo Therapeutics. "With symptoms that last on average over seven years, there is still a critical need for an effective, non-hormonal treatment that has the efficacy of estrogens but without the increased risks of cancer or cardiovascular disease."

About MLE-301

MLE-301 is a neurokinin 3 receptor (NK3R) antagonist that is being developed as a potential treatment of vasomotor symptoms (VMS), commonly known as hot flashes and night sweats, in menopausal women. NK3R plays a key role in regulating the activity of KNDy (kisspeptin/NKB/dynorphin) neurons, which has been shown to participate in the generation of VMS. By inhibiting the NK3R signaling on the KNDy neurons and potentially other NK3R-expressing neurons that propagate heat dissipation signals through the hypothalamus, MLE-301 aims to reduce the effects of hyperactive KNDy neurons and thereby decrease the frequency and severity of vasomotor symptoms.

About Millendo Therapeutics, Inc.

Millendo Therapeutics is a clinical stage biopharmaceutical company primarily focused on developing novel treatments for endocrine diseases where current therapies do not exist or are insufficient. Millendo seeks to create distinct and transformative treatments where there is a significant unmet medical need. The company is currently advancing MLE-301 for the treatment of vasomotor symptoms associated with menopause. For more information, please visit www.millendo.com.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this press release regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These include statements with respect to the Phase 1 clinical trials for and the potential clinical impact of MLE-301 on menopausal vasomotor symptoms, and, therefore, you are cautioned not to place undue reliance on them. Such forward-looking statements are based on Millendo's expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including that Millendo has incurred significant losses since inception, Millendo has a limited operating history and has never generated any revenue from product sales, Millendo will require additional capital to finance its operations, Millendo's future success is dependent on the successful clinical development, regulatory approval and subsequent commercialization of current and any future product candidates, preclinical studies or earlier clinical trials are not necessarily predictive of future results and the results of Millendo's clinical trials may not support Millendo's product candidate claims, Millendo may encounter substantial delays in its clinical trials or Millendo may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside Millendo's control, Millendo's product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, or limit their commercial potential, Millendo faces substantial competition and Millendo's business, preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic. You should refer to the risk factor disclosure set forth in the periodic reports and other documents Millendo files with the Securities and Exchange Commission available at www.sec.gov, including without limitation Millendo's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2020.

New factors emerge from time to time and it is not possible for Millendo to predict all such factors, nor can Millendo assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements included in this press release are based on information available to Millendo as of the date of this press release. Millendo disclaims any obligation to update such forward-looking statements to reflect events or circumstances after the

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