Noema Pharma Announces Phase 2a Study Results with Cendifensine in Women with Vasomotor Symptoms (Hot Flashes) Due to Menopause

Cendifensine demonstrates 92% reduction in number of hot flashes

Basel, Switzerland and Boston, MA – November 6, 2025 – Noema Pharma AG today announced positive topline results from a Phase 2a, open-label study evaluating cendifensine in menopausal women experiencing moderate-to-severe vasomotor symptoms (VMS), including hot flashes and night sweats. The results suggest that cendifensine may be an effective and well-tolerated, non-hormonal therapeutic option for women experiencing VMS due to menopause. Cendifensine (formerly known as NOE-115) is a novel, broad-spectrum monoamine modulator concurrently targeting three major neurotransmitters, with potential to address temperature dysregulation and additional menopausal symptoms.

"These data suggest that cendifensine could offer an effective non-hormonal treatment for the millions of women experiencing moderate-to-severe hot flashes and night sweats," said Ilise Lombardo, MD, Chief Executive Officer of Noema Pharma. "Through its novel mechanism, cendifensine may provide a differentiated approach to treating vasomotor symptoms, with potential to benefit additional symptoms as well. We are eager to advance this program into a Phase 2b study next year."

The Phase 2a study (NOE-PPM-201) enrolled women with menopause experiencing at least seven moderate-to-severe hot flashes per day. Thirty-five women were enrolled into this 12-week open-label study receiving target doses of either 30 mg daily or 60 mg daily. Safety, tolerability, and efficacy of cendifensine on VMS frequency and severity were assessed, as were changes in associated symptoms including mood, food cravings, fatigue and weight.

Treatment with the 30 mg dose resulted in the following outcomes:

- A mean 92.3% reduction from baseline to Week 12 in daily frequency of moderate-to-severe hot flashes, with a mean reduction of 12.3 daily hot flashes

(LS mean adjusted p<0.001).
- A mean 59.2% reduction from baseline to Week 12 in VMS severity, with mean reduction of 1.4 (LS mean adjusted p<0.001).
- A median reduction in weight of 2.5 kg at 12 weeks.
- Cendifensine showed improvements across additional menopausal symptoms, including mood, food cravings, and fatigue.
- The treatment benefits experienced by those in the 60 mg cohort were similar to those in the 30 mg cohort.

Daily treatment with cendifensine was generally well tolerated across all dose cohorts. Adverse events were mild-to-moderate with no serious adverse events reported.

"With 27 million women in the U.S. experiencing menopause, there remains a significant need for innovative, non-hormonal treatment options for those struggling with moderate-to-severe vasomotor symptoms," said Dr. Rebecca Dunsmoor-Su, MD, Chief Medical Officer for Gennev and an investigator in the NOE-PPM-201 study. "Many existing therapies are limited by medical constraints, stigma, or narrow symptomatic relief, particularly across the broader range of symptoms that women experience during the menopause transition. I look forward to future data exploring the full therapeutic potential of this novel approach, which may target multiple moderate-to-severe CNS-mediated menopausal symptoms."

About Cendifensine

Cendifensine (formerly NOE-115) is an oral, potential first-in-class, broad-spectrum monoamine modulator being developed for vasomotor symptoms (VMS) associated with menopause. It is designed to rebalance and selectively enhance monoamine activity across serotonin, norepinephrine, and dopamine, offering a novel non-hormonal approach to addressing temperature dysregulation and potentially other menopausal symptoms such as mood, fatigue, food cravings, and weight gain.

About Noema Pharma

Noema is developing a late-stage portfolio of oral, small molecule therapeutics with well-characterized mechanisms and distinct features that offer unique therapeutic advantages for neurological and other disorders. The Company is advancing three programs in parallel across orphan and large-market indications, targeting therapeutic areas of high unmet need and limited competition—each with blockbuster potential. Noema was founded by the leading venture capital firm Sofinnova Partners and is supported by the current investors including EQT,

Forbion, Gilde Healthcare, Invus, Jeito Capital, Polaris Partners and UPMC Enterprises. Learn more at www.noemapharma.com.

Investor Contact:

Michael Samar
Chief Financial Officer
Noema Pharma
info@noemapharma.com

Media Contact:

Julia Deutsch
Lyra Strategic Advisory
Jdeutsch@lyraadvisory.com

← View All News & Events