Objective

- Vasomotor symptoms (VMS) in menopausal women can be bothersome1-3 and negatively impact quality of life,1 sleep,1,4 work productivity4,6
- Difficulty sleeping is a common complaint of postmenopausal women,2,3 and has been associated with VMS7-10

Methods

Study Design

- The REPRISE trial (NCT01492462) was a randomized, double-blind, placebo-controlled, multicenter, phase 3 trial of E2/P4 capsules in postmenopausal women11
- Healthy menopausal women (aged 45-80 years) BM2 (34 kg/m2) were eligible. Key inclusion and exclusion criteria have been previously reported11

Figure 1. Weekly improvement in frequency and severity of moderate to severe hot flushes

MENDEL “difficulty sleeping”

- The MENDEL difficulty sleeping item (question #14) was rated using a 7-item Likert scale ranging from “Not at all bothered” (score of 2) to “Extremely bothered” (score of 8) if difficulty sleeping was experienced; if not experienced, the score was set to 1

Figure 3. Pathway disposition

Figure 2. Improvement in the Medical Outcome Study (MOS) Sleep total score

Figure 5A

Conclusions

- E2/P4 (1/100 and 0.5/50) improved sleep as measured by MENDOL. These data support previous reports of sleep improvement due to decreases in the frequency and severity of moderate to severe hot flushes and has been published as MENDOL Sleep score in the REPLENISH trial

- Overall, women <55 years had more significant and sustained improvements in the MENDEL difficulty sleeping assessment with E2/P4 (1/100 and 0.5/50) vs placebo compared with women ≥55 years, which may be partly due to a larger placebo response in women ≥55 years

- As the first combined bioidentical E2/P4 oral product approved by the FDA, 1 mg E2/100 mg P4 (Bijuva), is a new and HT option for postmenopausal women with moderate to severe VMS and a uterus, including the estimated millions15,16 of US women using unapproved compounded bioidentical hormones

References