Effects of TX-001HR in Women with <50 Moderate to Severe Hot Flushes per Week

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Introduction

• Vasomotor symptoms (VMS) are a common complaint of postmenopausal women.1,2
• Moderate to severe VMS can be effectively treated with FDA-approved hormone therapy (HT).3
• While most women do not meet the FDA criteria for ≥50 moderate to severe VMS per week, they are still bothered by their VMS.

Methods

Study Design

The REPLENISH trial (NCT01942668) was a phase 3, randomized, double-blind, placebo-controlled, multicenter trial that evaluated the safety and efficacy of four E2/P4 doses in postmenopausal women.4

• In October 2018, the FDA approved the 1 mg E2/100 mg P4 capsules as a treatment for moderate to severe VMS.

Objective

To evaluate the effects of E2/P4 on VMS frequency and severity in women with <50 moderate to severe VMS/week.

Results

VMS Frequency and Severity

• Baseline mean number of VMS in the VMS-non-substudy was 24.4±27.6 per week and mean severity score was 2.8±3.3.

• Women treated with E2/P4 doses had improvements from baseline in (Figure 4):
  - Severity of 11.8-16.2 VMS at week 4 and 16.6-19.5 VMS at week 12
  - Severity of 0.84-0.88 points at week 4 and 0.97-1.37 points at week 12
  - Women treated with E2/P4 doses had mean percent improvements from baseline in (Figure 5):
    - Frequency of 44%-65% at week 4 and 67%-80% at week 12
    - Severity of 28%-38% at week 4 and 43%-60% at week 12

Conclusions

• The magnitude of improvements in frequency and severity observed with E2/P4 in women with <50 moderate to severe VMS/week was similar to the significant improvements previously reported (Lobo et al, 2018) in women with ≥50 moderate to severe VMS/week.

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• A limitation of this analysis was that there was no placebo group in the VMS-non-substudy.

• The benefits of an oral E2/P4 capsule may extend to women who have less frequent moderate to severe VMS than what is typically studied and required for regulatory approval, but similar to what most women in the general population experience while going through menopause.

References


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