Improvement in Postmenopausal Sexual Dysfunction with TX-004HR as Measured by FSFI

Ginger D Constantine, MD,1 Shell Graham, PhD,2 Brian Bernick, MD,3 Gina Gasper,2 and Sebastian Mirkin, MD2
1EndoRheum Consultants, LLC, Malvern, PA; 2TherapeuticsMD, Boca Raton, FL

Introduction

- Vulvar and vaginal atrophy (VVA) is a chronic, progressive condition associated with the loss of estrogen in menopause
- VVA affects up to 69% of postmenopausal women1 and clinically manifests as symptoms of vaginal dryness, irritation, dysuria, and pain (dyspareunia) or bleeding with sexual activity,2 which can negatively affect female sexual function.3
- VVA symptoms interfere with sexual activity and satisfaction,4 which can influence quality of life.5
- Women with female sexual dysfunction (FSD) are almost 4 times more likely to have VVA than those without FSD.6

Methods

- The REJOICE Trial recently demonstrated TX-004HR to be clinically efficacious and safe for treating moderate-to-severe VVA and symptoms of dyspareunia, vaginal dryness, and vulvar and/or vaginal itching or irritation1

Study Participants

- 764 postmenopausal women were randomized to 4 µg (n=191), 10 µg (n=191), or 25 µg (n=192) vaginal E2 softgel capsules or placebo (n=192)
- Majority of the women were white (87%) with a mean age of 59 years (n=153)

Results

Table 1: Demographic and Baseline characteristics in the MITT population (N=764)

<table>
<thead>
<tr>
<th>Age, years</th>
<th>Mean±SD</th>
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<tbody>
<tr>
<td>4 µg (n=194)</td>
<td>59.8±6.0</td>
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<tr>
<td>10 µg (n=193)</td>
<td>58.6±6.3</td>
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<tr>
<td>25 µg (n=193)</td>
<td>58.8±6.2</td>
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<tr>
<td>Placebo (n=192)</td>
<td>59.6±6.0</td>
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FSFI Domain Scores

- TX-004HR (10 µg and 25 µg) had a significantly greater effect on total FSFI score (P=0.0003 vs placebo. *)
- All 3 TX-004HR doses were comparable to placebo in their effect on the FSFI domains of desire and orgasm (Figure 2)

Conclusions and Clinical Implications

- TX-004HR (10 µg and 25 µg) had a significantly greater effect on total FSFI score and the majority of the FSFI domain scores compared with placebo.
- The large placebo response observed here could be attributed to the presence of placebo effect, which can lead to improvements in sexual function in both groups, including placebo.
- TX-004HR significantly improved FSFI arousal (P=0.0073) and satisfaction (P=0.0003) in postmenopausal women with VVA.

References


Disclosures

- All authors report no potential conflicts of interest. No potential conflicts of interest to disclose.

Poster presented at the 2016 ACOG Annual Meeting, May 14-17, Washington, DC