Elagolix Reduced Dyspareunia and Improved Health-related Quality of Life in Premenopausal Women with Endometriosis-associated Pain

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Introduction: Dyspareunia is a common symptom of endometriosis, and can impact personal relationships, self-image and quality of life. Elagolix is an oral, gonadotropin-releasing hormone receptor antagonist. We analyzed the effect of elagolix on dyspareunia in a pooled data set of >1600 women with endometriosis-associated pain.

Patients and Methods: Efficacy data from two 6-month, randomized, placebo-controlled trials (Elaris Endometriosis [EM]-I and EM-II) of elagolix (150mg QD or 200mg BID) in women with endometriosis, dysmenorrhea and non-menstrual pelvic pain (randomized and treated, N=1686) were pooled. Women assessed dyspareunia in a daily electronic pain impact e-diary (none, mild, moderate, severe, or not applicable) and the impact of endometriosis on pain with sexual intercourse [30-item Endometriosis Health Profile [EHP-30] questionnaire sexual intercourse dimension [never, rarely, sometimes, often, always] with monthly recall; responses normalized to 0-100 scale [best to worst]). Dyspareunia responders were defined as having stable/decreased rescue analgesic use and, based on a receiver operating characteristics analysis, a clinically meaningful decrease from baseline to month 6 in e-diary dyspareunia score; significant differences vs. placebo were based on a logistic regression model. Significant differences vs. placebo for the mean change from baseline in EHP-30 sexual intercourse dimension score were based on an ANCOVA model. Adverse events were recorded.

Results: Most women were white (88%) with a mean age of 32 years (range, 18-49). Of the 1384 women who reported sexual activity (≥1 day of none, mild, moderate, or severe dyspareunia) in the 35-day baseline interval, 48% reported ≥1 day of severe dyspareunia. Of the women who reported ≥1 day of severe dyspareunia at baseline and sexual activity during month 6, ≥1 day of none/mild dyspareunia, and zero days of moderate/severe dyspareunia during month 6 was reported by 21% of placebo (n=197), 33% of 150mg QD elagolix (n=141) and 54% of 200mg BID elagolix (n=134). Of the women who reported sexual activity at baseline and month 6, the proportion of dyspareunia responders were 36% for placebo (n=524), 40% for 150mg QD elagolix (n=350, p=0.272), and 53% for 200mg BID elagolix (n=326, p<0.001). Mean [SD] EHP-30 sexual intercourse dimension scores at baseline were similar [placebo, 61.9 [25.4]; 150mg QD elagolix, 60.3 [26.7]; 200mg BID elagolix, 62.0 [24.8]). The least-squares mean (SE) changes from baseline to month 6 EHP-30 scores on the sexual intercourse dimension were similar at baseline (placebo, 61.9 [25.4]; 150mg QD elagolix, 60.3 [26.7]; 200mg BID elagolix, 62.0 [24.8]). Of the 1384 women who reported sexual activity at baseline and sexual activity during month 6, 28.7 (1.3) for placebo (n=322), -16.6 (1.6) for 150mg QD elagolix (n=234; p=0.064), and -28.7 (1.6) for 200mg BID elagolix (n=234; p<0.001). As previously reported, elagolix-treated women had hypoestrogenic events consistent with the mechanism of action, though few discontinued due to these events.

Conclusions: Nearly half of the women who reported sexual activity in the 35-day baseline interval had ≥1 day of severe dyspareunia, thus confirming the importance of assessing changes in dyspareunia. Compared to placebo, 200mg BID elagolix significantly improved dyspareunia in women with endometriosis-associated pain, which was accompanied by an improvement in the health-related quality of life for sexual intercourse dimension.

Keywords : dyspareunia, clinical trial, GnRH, antagonist, sexual intercourse, pelvic pain
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