Objective: Oral ospemifene, a tissue selective estrogen agonist/antagonist, is approved for the treatment of moderate to severe postmenopausal dyspareunia, a symptom of vulvar and vaginal atrophy (VVA). The objective of this analysis was to assess ospemifene 60 mg/day on the efficacy on the vaginal epithelium and self-identified most bothersome symptoms (MBS) of VVA in the overall population as well as subpopulations.

Design: Data from 4 randomized, double-blind placebo-controlled trials were analyzed for the co-primary endpoints of change in percentage of cells (superficial, parabasal) in the Maturation Index (MI) and in vaginal pH from Baseline to Week 12/LOCF. Change in severity for MBS from Baseline to Week 12/LOCF (dyspareunia, vaginal dryness) was analyzed in the two trials which included MBS as a co-primary endpoint. To assess population effects, pooled data from the placebo-controlled trials were analyzed for age, race, prior HRT use and uterine status of participants.

Results: Changes from Baseline to Week 12 in the % of superficial cells, % of parabasal cells and vaginal pH demonstrated statistically significant improvement vs placebo in each trial (p<0.05). For MBS, ospemifene demonstrated significant improvement in severity at Week 12 for dyspareunia in both trials (p<0.05); and in one trial for dryness with numerical improvement in the other.

At Week 12, for all subpopulations numerical improvements in all endpoints were observed in the ospemifene group compared to placebo.

Conclusion: Overall, ospemifene provided significant and reproducible benefit for physiological changes and symptoms associated with VVA and improvements remained consistent between and within the subpopulations of age, race, prior HRT use and uterine status. Oral ospemifene 60mg is an effective treatment option for postmenopausal women with symptoms (ie, dyspareunia) of VVA.