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Bremelanotide (BMT) for Hypoactive Sexual Desire Disorder (HSDD): Efficacy Analyses from the RECONNECT Studies

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Context: When accompanied by distress, diminished or lack of desire for sexual activity may be diagnosed as HSDD, a common female sexual dysfunction.
Objective: Evaluate BMT as a treatment for HSDD.
Methods: Two Phase 3 trials: core phase included a 4-week screening, 4-weeks of single-blind placebo, and a 24-week double-blind period.
Subjects: Premenopausal women with HSDD.
Interventions: BMT 1.75 mg or placebo self-administered SC using an auto-injector, as-desired, prior to sexual activity.
Main Outcome Measures: Co-primary endpoints: change in the desire domain of the Female Sexual Function Index (FSFI-D) and the Female Sexual Distress Scale-Desire/Arousal/Orgasm (FSDS-DAO) score for being bothered by low sexual desire (Item 13) at 24-weeks Secondary endpoints: change from baseline to end of study (EOS) in the FSFI total, arousal, lubrication, orgasm, and satisfaction scores; FSDS total and bother scores; Women's Index of Treatment Satisfaction (WITS-9) score; self-assessed benefit; and satisfying sexual event (SSE) items of the Female Sexual Encounter Profile-Revised (FSEP-R).
Results: Primary efficacy population: 1202 women (mean age 39 years; >80% white; ?68% with HSDD + decreased arousal). In both studies, compared with placebo, women using BMT had significantly (P?0.001) increased scores on the FSFI-D indicating an increase in desire and a significant (P?0.01) reduction in their Item 13 score on the FSDS-DAO indicating a reduction in distress related to low sexual desire. On secondary outcomes, BMT was associated with significant improvements from baseline to EOS in FSFI total, arousal, lubrication, orgasm, and satisfaction domain scores (P?0.01); FSDS total and bother scores (P?0.01); and WITS-9 score and self-assessed benefit (P<0.0001). FSEP-R scores for satisfaction with desire and arousal were significantly improved only in Study 301 (P?0.01). Changes in the number of SSEs did not differ significantly from placebo; however, women using BMT reported a higher percentage of sexual encounters as satisfactory. The most frequent adverse events were mild or moderate nausea, flushing, and headache.
Conclusions: Bremelanotide is associated with a clinically meaningful and statistically significant improvement in desire and decrease in distress in premenopausal women, both hallmark characteristics of HSDD compared to placebo at 24 weeks. BMT is also associated with improvements in other components of sexual functioning; arousal, lubrication, and orgasm.

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