Introduction

Acquired female sexual dysfunctions (FSD) encompass a range of conditions classified by the International Index of Erectile Dysfunction (IIEF), including impairments of sexual desire (HSDD) and sexual arousal (FSAD). Key efficacy outcomes were subjected to pre-specified statistical significance versus placebo

Methods

Subject Study. All subjects were premenopausal women with a ≥6-month duration of HSDD and/or FSAD diagnosed by a qualified clinician using validated instruments and a diagnostic interview. Each subject was in a stable relationship and was willing to be sexually active at least once per month.

Study Design. After a 4-week screening period to confirm the presence of FSD, subjects received a single-dose, in-clinic placebo or active drug treatment (baseline period), followed by 4 weeks of single-blind, at-home placebo (week 1), and then 4 weeks of single-blind, at-home drug self-dosing (week 2). For treatment groups with a ≥6-month duration of HSDD and/or FSAD diagnosed by a qualified clinician using validated instruments and a diagnostic interview. Each subject was in a stable relationship and was willing to be sexually active at least once per month.

Conclusions

In premenopausal women with FSD, BMT self-administered subcutaneously on all aches, as-needed basis exhibited dose-dependent efficacy with a 28-day recall period, resulting in a decrease in distress and an improvement overall in sexual function as compared to placebo. Safety was good, with no marked dosage-dependence. Of the 3 BMT users who reported serious AEs (SAEs), each had a history of the SAE type (asthma exacerbation, ventral incisional hernia, non-cardiac chest pain). None of the SAEs was considered to be related to study drug.