Introduction

Acquired female sexual dysfunctions (FSD) are common, distressing conditions with a strong negative impact on quality of life.1 Distress in women with hypoactive sexual desire disorder (HSDD) or female sexual arousal disorder (FSAD) may be managed by recreational use of intranasal PT-141, a melanocortin receptor agonist.4-7 No marketed dosage is available, and there is no regulatory approval.8

Methods

Study Subjects. All subjects were required to have a 3-month duration of ‘‘hyposexual desire disorder’’ (HSDD)9 or female sexual arousal disorder (FSAD)10 diagnosed by a qualified clinician using validated instruments and a diagnostic interview. Each subject was also required to be sexually active at least once monthly and be willing to be sexually active at least once per month.

Study Design. Subjects underwent a no-treatment diagnosis–confirmation month, followed by a single-blind in-clinic placebo dose and then 4 weeks of single-blind, at-home placebo self-dosing, which constituted the study’s baseline period (a novel design devised to address the substantial placebo effect often seen in FSD studies). Subjects were then randomized to double-blind in-clinic (placebo or active: 1.25 or 1.75 mg twice as in-clinic doses (a week apart)) and then for 3 months of at-home, as-needed self-dosing (by pre-filled syringes) –45 minutes prior to anticipated sexual activity (not exceeding 1 dose per day or 16 doses during a 4-week period). The design is schematically shown in Figure 1.

Results

Table 1. Subjects’ Baseline Characteristics

| Characteristic | n=87 | n=93 | n=88 | n=99 | n=197
|---------------|-----|-----|-----|-----|-----|
| Age, mean (SD) | 47 (12) | 47 (12) | 47 (12) | 47 (12) | 47 (12)
| Race, n (%): | | | | | 
| White | 82 (94) | 88 (94) | 86 (98) | 92 (93) | 184 (93)
| Black | 6 (7) | 4 (4) | 2 (2) | 5 (5) | 14 (7)
| Other | 1 (1) | 1 (1) | 1 (1) | 1 (1) | 4 (2)
| Education level, n (%): | | | | | 
| High school or lower | 40 (46) | 42 (45) | 43 (49) | 46 (47) | 121 (61)
| Some college/technical school | 19 (22) | 20 (22) | 21 (24) | 23 (24) | 64 (32)
| Bachelor’s degree | 20 (23) | 22 (24) | 18 (20) | 19 (20) | 69 (35)
| Advanced degree | 8 (9) | 9 (10) | 4 (5) | 7 (8) | 28 (14)
| BMI, mean (SD) | 27.5 (4.7) | 27.5 (4.7) | 27.5 (4.7) | 27.5 (4.7) | 27.5 (4.7)
| SEDLS, mean (SD) | 11.3 (3.5) | 11.3 (3.5) | 11.3 (3.5) | 11.3 (3.5) | 11.3 (3.5)
| FSAD, n (%): | | | | | 
| Yes | 3 (3) | 5 (5) | 4 (4) | 3 (3) | 15 (8)
| No | 84 (97) | 88 (95) | 84 (96) | 96 (97) | 179 (92)
| HSDD, n (%): | | | | | 
| Yes | 78 (88) | 87 (93) | 79 (89) | 89 (90) | 238 (122)
| No | 9 (10) | 6 (6) | 9 (11) | 10 (10) | 24 (12)

Efficacy Analyses. FSDS-DAO scores were obtained at baseline and after 1, 2, and 3 months of at-home study-drug use. Mean score changes from baseline to 12 months were analyzed by Van Elteren test, including pre-planned comparisons between findings for placebo and pooled findings for the two highest BMT doses (125 and 175 mg).

About the FSDS-DAO. The FSDS-DAO is a 15-item questionnaire based on a 13-item instrument, the Female Sexual Distress Scale–Revised (FSDS-R), which was designed to assess sexual distress over a 30-day recall period. Of the two additional FSDS-DAO clinical concerns (‘‘I am often too tired’’ ‘‘I feel too sad’’ ‘‘I am often too depressed’’ ‘‘You can’t talk to me about this problem’’), two concerns were on a Likert-type scale ranging from 0 (‘‘Never’’) to 4 (‘‘Always’’). The total score is the sum of responses, and ranges from 0 to 60; a higher score indicates increased sexual distress. Clinical data and detailed evidence supports the test-retest reliability and construct validity of the FSDS-R in women with HSDD.11 In the present study, the FSDS-DAO demonstrated acceptable internal consistency, test-retest reliability, construct validity, discriminant validity, and predictive validity in women with FSAD and/or HSDD (Patel data). For the mITT population, baseline values of FSDS measures are summarized in Table 2. The mean baseline FSDS-DAO total score was 35.0 to 33.3, depending on treatment group, compared with 25.4 to 25.5 baseline FSDS-R overall improvement pattern showed dose-dependence. For the mITT population, baseline values of FSDS measures are summarized in Table 2. The mean baseline FSDS-DAO total score was 35.0 to 33.3, depending on treatment group, compared with 25.4 to 25.5 baseline FSDS-R overall improvement pattern showed dose-dependence. For the mITT population, baseline values of FSDS measures are summarized in Table 2. The mean baseline FSDS-DAO total score was 35.0 to 33.3, depending on treatment group, compared with 25.4 to 25.5 baseline FSDS-R overall improvement pattern showed dose-dependence. For the mITT population, baseline values of FSDS measures are summarized in Table 2. The mean baseline FSDS-DAO total score was 35.0 to 33.3, depending on treatment group, compared with 25.4 to 25.5 baseline FSDS-R overall improvement pattern showed dose-dependence. For the mITT population, baseline values of FSDS measures are summarized in Table 2. The mean baseline FSDS-DAO total score was 35.0 to 33.3, depending on treatment group, compared with 25.4 to 25.5 baseline FSDS-R overall improvement pattern showed dose-dependence.