Efficacy of the Investigational Drug Bremelanotide in the RECONNECT Studies

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Background

• The most common sexual concern experienced by women is low sexual desire or lack of desire for sexual activity

• When assessed by bothersome desire, this may be diagnosed as hypoactive sexual desire disorder (HSDD)

• The etiology of HSDD remains unknown; however, one hypothesis is based on the pathophysiology of hypothalamic hypogonadism, hypothyroidism, and endocrine abnormalities that lead to low sexual desire (Table 1).

Mechanism of Sexual Response

• Excitatory signals are regulated by dopamine (DA), norepinephrine (NE), estrogen, and the melanocortin system.

• The presence of any female sexual dysfunction other than HSDD diagnosis

• Women’s Inventory of Treatment Satisfaction (WITS-9)

• SSE items from the Female Sexual Encounter Profile-Revised (FSEP-R)

• FSDS-DAO total and arousal scores

Study Participants

• Healthy premenopausal, nonpregnant women ≥18 years of age, currently in a stable relationship at least 6 months

• Double-blind core phase, including active treatment (BMT) and placebo groups

• Willing to engage in sexual activities 3–7 days per week during the study

• Had ≥0.09; **p < 0.001; ***p < 0.0001

Key Outcome Measures

Co-Primary Endpoint

• Change from baseline to end-of-study (EOD) in the FSFI desire domain score

Secondary Endpoint Measures

• FSFI total, arousal, lubrication, orgasm, and satisfaction domain scores

• SDE items from the Female Sexual Encounter Profile-Revised (FSEP-R)

• Women’s Inventory of Treatment Satisfaction (WITS-9)

• Question #3 on the General Assessment Questionnaire

Results

Participants and Baseline Demographics

• The primary efficacy population (mITT) comprises the 1262 women who completed at least 1 month of the Core phase of Study 301

• Participants were mostly white (84%) and non-Hispanic; Latin (16%) in both studies (Table 1).

Secondary Endpoint Analyses

• On the FSFI, BMT was also associated with significant increases in FSFI-D scores

Figure 6. Mean Change in FSDS-DAO Total Score and Arousal Domain Scores: Baseline to End of Core Phase

• BMT, bremelanotide; WITS-9, Women’s Inventory of Treatment Satisfaction.

Safety

• Most adverse events (AEs) were mild or moderate

• Treatment-emergent AEs led to treatment discontinuation in approximately 18% of women taking BMT

• Most of the BMT AEs causing study withdrawal were headaches, nausea, and dizziness in 3% (17% and 7% in Studies 301 and 302, respectively)

• BMT’s safety profile was consistent with prior clinical trial experience; nausea or unusual taste was identified as an unexpected finding in the placebo group of Study 201.

Conclusions

• Bremelanotide, an investigational self-administered drug used as-desired prior to sexual activity, provided a clinically meaningful and statistically significant improvement in the key aspects of HSDD and desire, and a decrease in distress related to low desire in premenopausal women diagnosed with generalized, acquired HSDD in 2 Phase 3 clinical trials. Bremelanotide appears to be generally well tolerated in this population.

References

3. Clayton AH, Pfaus JG. J Sex Marital Ther. 2010;36.1