Efficacy of Bremelanotide Among Women Completing the Core Phase of the RECONNECT Studies

Sheryl Kingsberg, Robin Kroll, John Lucas, Robert Jordan, Carl Spana

1Case Western Reserve University School of Medicine, Cleveland, OH, USA; 2Seattle Women’s Health, Research, Gynecology, Seattle, WA, USA; 3Palatin Technologies, Inc, Cranbury, NJ, USA

Background

Female sexual dysfunctions (FSD) comprise a group of conditions with physiological, psychological, and social components.1 The most common sexual concern expressed by women with FSD is diminished or lack of desire for sexual activity.2–5 Female sexual dysfunctions (FSD) comprise a group of conditions with physiological, psychological, and social components.1 The most common sexual concern expressed by women with FSD is diminished or lack of desire for sexual activity.2–5

Study Design

The RECONNECT studies comprise 2, identical, randomized, Phase 3, placebo-controlled, multicenter trials (NCT0333071 [Study 301] and NCT03339860 [Study 302]). The Core phase of the trials includes a 1-month no-drug treatment period, a 1-month single-blind placebo treatment period (to establish baseline), and a 24-week double-blind treatment period. Both trials also have an ongoing 52-week open-label extension period (Figure 1).

Study Objectives

To evaluate the safety and efficacy of BMT 1.75 mg in female patients with hypoactive sexual desire disorder.6

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Study Participants

Participants were randomized (1:1) to either placebo or BMT 1.75 mg, self-administered, subcutaneously using an auto-injector (Figure 2), as desired, prior to sexual activity.

Figure 2. Auto-injector

Key Outcome Measures

Coprimary Efficacy Endpoints

• Change from baseline to end-of-study (EOS) in the Female Sexual Function Index (FSFI) total score (primary endpoint).

• Change from baseline to EOS in the desire domain of the FSFI.

Responder Analysis Based On

• Participants had complete responses (c/n ≥ 0.5 on a 0 (poor) to 1 (excellent) scale) in 9 of the 13 items of the FSFI-D domain.

Study Population

• Most of the bremelanotide AEs causing withdrawal were nausea (9.9% of patients in Study 301 and 6.6% in Study 302) and vomiting (1.5% of patients in Study 301, and 0.7% in Study 302).

• Bremelanotide’s safety profile was consistent with prior clinical trial experience; no new or unusual safety issues were identified for the double-blind period.

• Bremelanotide has no known alcohol interaction.7

References


Conclusions

• Treatment with BMT over the 6-month Core phase of the RECONNECT study was associated with clinically meaningful and statistically significant improvement in desire and a decrease in negative/fearful self-hypothesized characteristics of HSDD.

• FSFI-D scores showed that BMT significantly decreased compared with placebo.

• FSDS-DAD item 13 scores in the BMT groups significantly decreased compared with placebo, indicating a decrease in distress related to low sexual desire.

• The MCID analyses in the RECONNECT study, using a woman's self-assessed benefit, provide support for the statistically significant numerical efficacy observed with BMT. BMT is clinically meaningful to women with HSDD.

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