Exit Survey of Women With Hypoactive Sexual Desire Disorder Treated With Bremelanotide in the RECONNECT Studies Demonstrated Meaningful Treatment Benefits

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Study Participants and Key Entry Criteria

Healthy, women-aged 18-50; diagnosed with HSDD at least 6 months prior to study entry; taking no OCPs, estrogen, or progesteron for at least 6 months prior to study entry; normal laboratory studies, with the exception of TSH; had to report at least 6 months of symptom severity prior to study entry; participated in a dose-escalation phase (if applicable); had to receive at least 1 dose of double-blind study medication; not pregnant, not breastfeeding.

Methods

Study Design

The RECONNECT studies (301 and 302) were multicenter, randomized, double-blind, placebo-controlled trials of BMT 1.75 mg (n=102) or placebo (n=35) over 12 weeks with an extension phase (if applicable); placebo (n=159) or BMT (n=256) for 1 year. The Core Phase was designed to measure treatment efficacy; the 12-week Treatment Phase was followed by an extension phase (if applicable). The Qualitative Exit Interview was conducted in Week 12 of treatment (after 4 weeks of blinded study medication). The Quantitative Exit Survey was conducted 1 month after completing the Core Study Phase (Week 16 of blinded study medication).

Study Participants

A total of 439 women completed the Core Phase (BMT 1.75 mg: n=102; placebo: n=35). During the Qualitative Exit Interview, 101 participants were asked if they wished to continue treatment if it were available by prescription after the study (BMT: 71%, placebo: 30%). During the Quantitative Exit Survey, 125 participants completed the survey at Week 16 of blinded study medication (BMT: 71%, placebo: 28%).

Results

Overall Experience

Most patients receiving BMT were interested in continuing with treatment and would recommend it to other patients. BMT was rated as “very good” or “good” by most patients, and the most common treatment-related adverse events were injection site pain and injection site reaction.

Experience With the Device

Overall, 60% of patients across both treatment groups rated the device “excellent” or “very good.”

Conclusions

Results from this exit survey showed that women receiving BMT consistently reported meaningful treatment benefits compared with placebo, supporting the positive efficacy and safety profile of BMT for HSDD. Participating patients would recommend BMT to other patients, and the most important aspects of treatment for many were not encountering side effects, partner satisfaction, overall satisfaction, and need for injection.

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Disclosures

PK has an employment at Eisai (2013–2016), which has provided consultancy services to Palatin. The other authors disclose no conflicts of interest.