Safety and Efficacy of Bremelanotide for HSDD in Women: RECONNECT Study
Open-Label Extension Phase Results

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Background

Bremelanotide (BMT), a novel cyclic 7-amino acid melanocortin-4-receptor agonist with high affinity for MC4R, is an investigational drug currently in development for the treatment of hypoactive sexual desire disorder (HSDD).

The RECONNECT studies comprise 3 identical, randomized, phase 3, placebo-controlled, multicenter trials (NCT02333071 [Study 301] and NCT02338960 [Study 302]) of BMT 1.75 mg administered subcutaneously (SC) in an autoinjector pen, as desired, for the treatment of HSDD in women (see Figure 1).

Results from the Core Study Phase have been reported previously. This presentation includes long-term safety and efficacy results from the RECONNECT Open-Label Extension (OLE) Study.

Methods

Study Participants

Participants had successfully completed the Core Study Phase of the studies, had no serious adverse events (SAEs) related to BMT, and met the eligibility criteria of the OLE Study Phase.

Key Outcome Measures

Safety was assessed through monitoring adverse events (AEs), clinical laboratory evaluation, and clinically sig

Efficacy assessments were similar to those in the Core Study Phase, but with no hierarchy of primary and secondary efficacy endpoints.

Table 1: Efficacy Assessments

<table>
<thead>
<tr>
<th>Measure</th>
<th>Description</th>
<th>Units</th>
<th>Timepoint</th>
<th>Type of Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSFI-D</td>
<td>Female Sexual Function Index – desire domain; 5 items</td>
<td>6-point Likert scale</td>
<td>Baseline, Week 4, Week 8, Week 24, Week 36, and Week 52</td>
<td>Continuous</td>
</tr>
<tr>
<td>FSDS-DAO</td>
<td>Female Sexual Distress Scale – Desire/Arousal/Orgasm; 3 items</td>
<td>6-point Likert scale</td>
<td>Baseline, Week 4, Week 8, Week 24, Week 36, and Week 52</td>
<td>Continuous</td>
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<tr>
<td>FSEP-R</td>
<td>Female Sexual Encounter Profile-Revised; 15 items</td>
<td>6-point Likert scale</td>
<td>Baseline, Week 4, Week 8, Week 24, Week 36, and Week 52</td>
<td>Continuous</td>
</tr>
</tbody>
</table>

Results

Baseline Characteristics

A total of 644 participants continued in the OLE Study Phase in Study 301 and 302. The baseline characteristics for the total number of BMT injections in the placebo-BMT and BMT-BMT groups were similar, respectively.

Safety

One subject developed a case of acute hepatitis. At the end of the last visit on study, subject had a serum alanine transaminase level of 40 U/L (very much better); assessed at each monthly clinic visit

In the randomized, placebo-controlled Core Study Phase, both studies met the prespecified co-primary endpoints with a statistically significant increase in desire (FSFI-D) and a decrease in distress (FSDS-DAO) compared with placebo in the BMT-BMT group.

Table 2: TEAEs in Open-Label Extension Phase (≥5% of Patients)

<table>
<thead>
<tr>
<th>TEAEa</th>
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<tbody>
<tr>
<td>Headache</td>
</tr>
<tr>
<td>Nausea</td>
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<tr>
<td>Sunburn</td>
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</tbody>
</table>

Conclusions

BMT, an investigational, self-administered, SC injection, was generally well tolerated.

The results from the OLE Study Phase provided additional support for the potential use of BMT as an effective treatment of HSDD in premenopausal women.

Acknowledgments

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References


Figure 1. Study Design

Figure 2. FSFI-D and FSDS-DAO Item 13* Scores Throughout RECONNECT Studies (OLE Study Population)

Table 2. TEAEs in Open-Label Extension Phase (≥5% of Patients)

Table 3. QAO Question 3 Scores

Figure 3. QAO Question 3 Scores

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