Treatment Satisfaction With Subcutaneous Bremelanotide Self-administered at Home by Premenopausal Women With Female Sexual Dysfunction: A Placebo-controlled Dose-ranging Study

Stanley E. Althof, Jeffrey Edelson, Robert Jordan

1Center for Marital and Sexual Health of South Florida, West Palm Beach, FL; 2Palatin Technologies, Inc., Cranbury, NJ
Disclosures

• Dr Althof has received research support or consulting fees from Abbott, Allergan, Bayer Healthcare, Eli Lilly, Palatin Technologies, Inc., Promescent, Sprout Pharmaceuticals, and Trimel Pharmaceuticals, Inc.

• Dr Edelson and Mr Jordan are employees and stockholders of Palatin Technologies, Inc.
First-in-class melanocortin-receptor-4 agonist
Developed by Palatin Technologies, Inc., for the treatment of female sexual dysfunction (FSD)
Novel mechanism of action activating endogenous pathways involved in sexual response
On-demand use with rapid onset of activity
Evaluated in 31 clinical studies in more than 2,500 people
• Phase 2B study to evaluate the efficacy and safety of BMT in premenopausal women with FSD

• Design:

<table>
<thead>
<tr>
<th>Study Week</th>
<th>In-clinic placebo dose</th>
<th>In-clinic study-drug doses</th>
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</thead>
<tbody>
<tr>
<td>1-2</td>
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Note: At-Home Placebo Self-Dosing period = Baseline
### Patient Reported Outcomes in FSD

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Items</th>
<th>Measure</th>
<th>Domains</th>
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</thead>
<tbody>
<tr>
<td>WITS-9</td>
<td>9</td>
<td>Patient completed; treatment satisfaction</td>
<td>Initiation/receptivity satisfaction, treatment satisfaction, and perceived partner satisfaction</td>
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<tr>
<td>FSFI</td>
<td>19</td>
<td>Patient completed; overall sexual function</td>
<td>Desire, arousal, lubrication, orgasm, satisfaction, and pain</td>
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<tr>
<td>FSDS-DAO</td>
<td>12</td>
<td>Patient completed; sexual dysfunction-related distress</td>
<td>Distress, arousal, and orgasm</td>
</tr>
<tr>
<td>SIDI-F</td>
<td>17</td>
<td>Clinician administered; severity of HSDD symptoms</td>
<td>Desire, general relationship satisfaction, mood, and fatigue</td>
</tr>
<tr>
<td>FSEP-R</td>
<td>10</td>
<td>Patient completed; episodic assessment of sexual function</td>
<td>Initiation, current level of desire/arousal, satisfaction with level of desire/arousal, lubrication, orgasm, conditions, SSE</td>
</tr>
</tbody>
</table>

FSDS-DAO, Female Sexual Distress Scale – Desire/Arousal/Orgasm; FSEP-R, Female Sexual Encounter Profile – Revised; FSFI, Female Sexual Function Index; HSDD, Hypoactive Sexual Desire Disorder; SIDI-F, Sexual Interest Distress Scale; SSE, Satisfying sexual encounter; WITS-9, Women’s Inventory of Treatment Satisfaction - 9
Treatment Satisfaction Differs from Efficacy

• Treatment satisfaction is the patient’s or partner’s **subjective** evaluation of how satisfied they are with the intervention
  • Captures treatment components not measured by treatment efficacy
  • May be correlated with efficacy
  • One important aspect of disease-specific quality-of-life
  • May be predictive of treatment continuation and/or dropout

• Efficacy is the **objective** measure of the maximum effect of a drug
Endpoints

• Change from baseline to end-of-study in the WITS-9 score
  – Total score
  – Domain scores
  • Satisfaction with sexual activity/interest
  • Perceived partner satisfaction
  • Treatment satisfaction
WITS-9: Total Score

*P<0.05
WITS-9: Satisfaction With Sexual Activity/Interest
WITS-9: Perceived Partner Satisfaction

Mean Change From Baseline

- Placebo
- 0.75 mg
- 1.25 mg
- 1.75 mg
- 1.25/1.75 mg pooled
WITS-9: Treatment Satisfaction

Mean Change From Baseline

Placebo  0.75 mg  1.25 mg  1.75 mg  1.25/1.75 mg pooled

*P<0.05  **P<0.01
Summary and Conclusion

• There was an increase in the total WITS-9 score with BMT 1.75 mg and 1.25/1.75 mg pooled
  – The increase was reflected primarily in the Treatment Satisfaction domain
• Treatment satisfaction is a predictor of compliance and continuation in treatment