

Truncated Depression Rating Scale Outcomes in the OLIVE Trial Exploring a V1bR Antagonist and a Genetic Selection Tool

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MAIN TAKEAWAYS

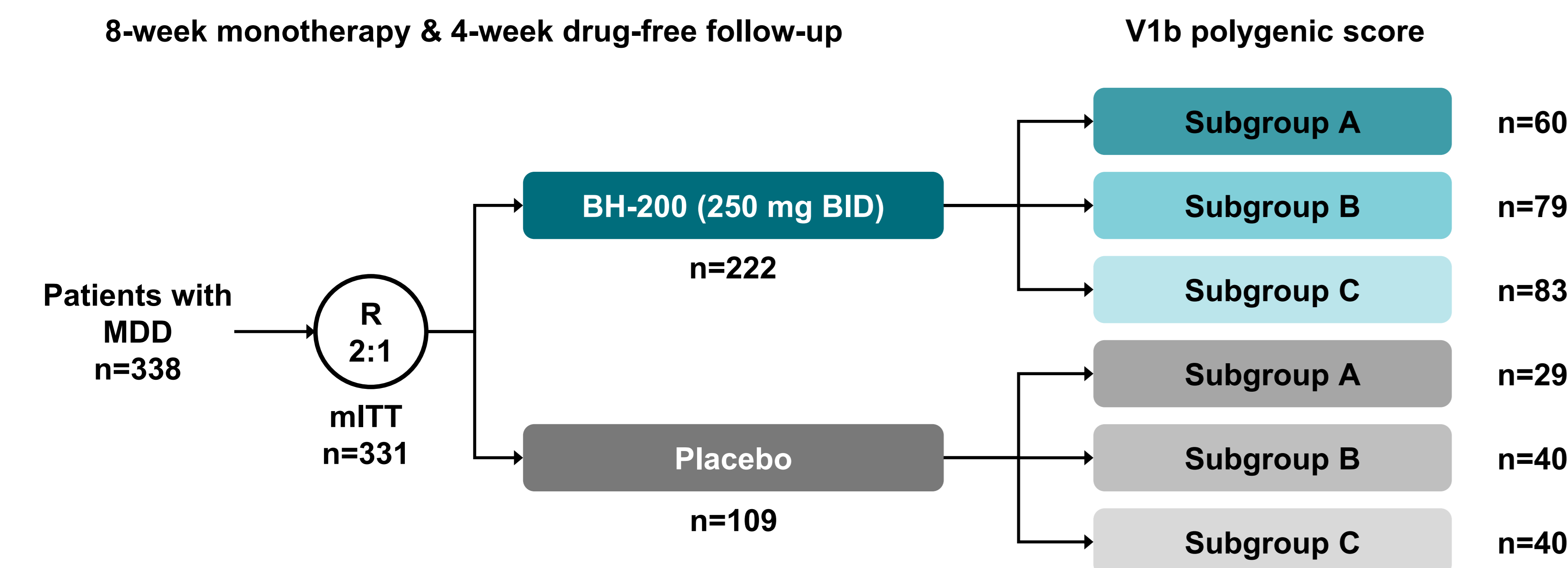
- BH-200 demonstrated a high standardized effect size after 8 weeks of treatment compared to placebo.
- The effect sizes were similar between the truncated scales and the full scales, findings at odds with the differences suggested in the literature.
- The correlation between full and truncated scales was comparable for MADRS and HAMD.

Background

Clinician-rated depression scales such as the Hamilton Depression Rating Scale (HAMD) and the Montgomery-Åsberg Depression Rating Scale (MADRS) are the current gold standards to measure efficacy in depression trials. However, the full 17-item HAMD (HAMD-17) and 10-item MADRS versions include items that may be weakly related to core depressive symptoms or show limited sensitivity to change. Truncated versions of both scales, focusing on the 6 core items each (HAMD-6 and MADRS-6), have been suggested to enhance signal detection [1, 2, 3]. In a pooled patient-level analysis of data from 6669 adults treated with either selective serotonin reuptake inhibitors or placebo in short-term trials in major depressive disorder (MDD), the standardized mean difference was 0.27 for HAMD-17 and 0.35 for HAMD-6 [4]. Here, we explored the sensitivity to detect efficacy of full and truncated scales in the placebo-controlled OLIVE trial testing BH-200 (a selective antagonist of vasopressin receptor V1bR) against placebo in MDD.

Patients and methods

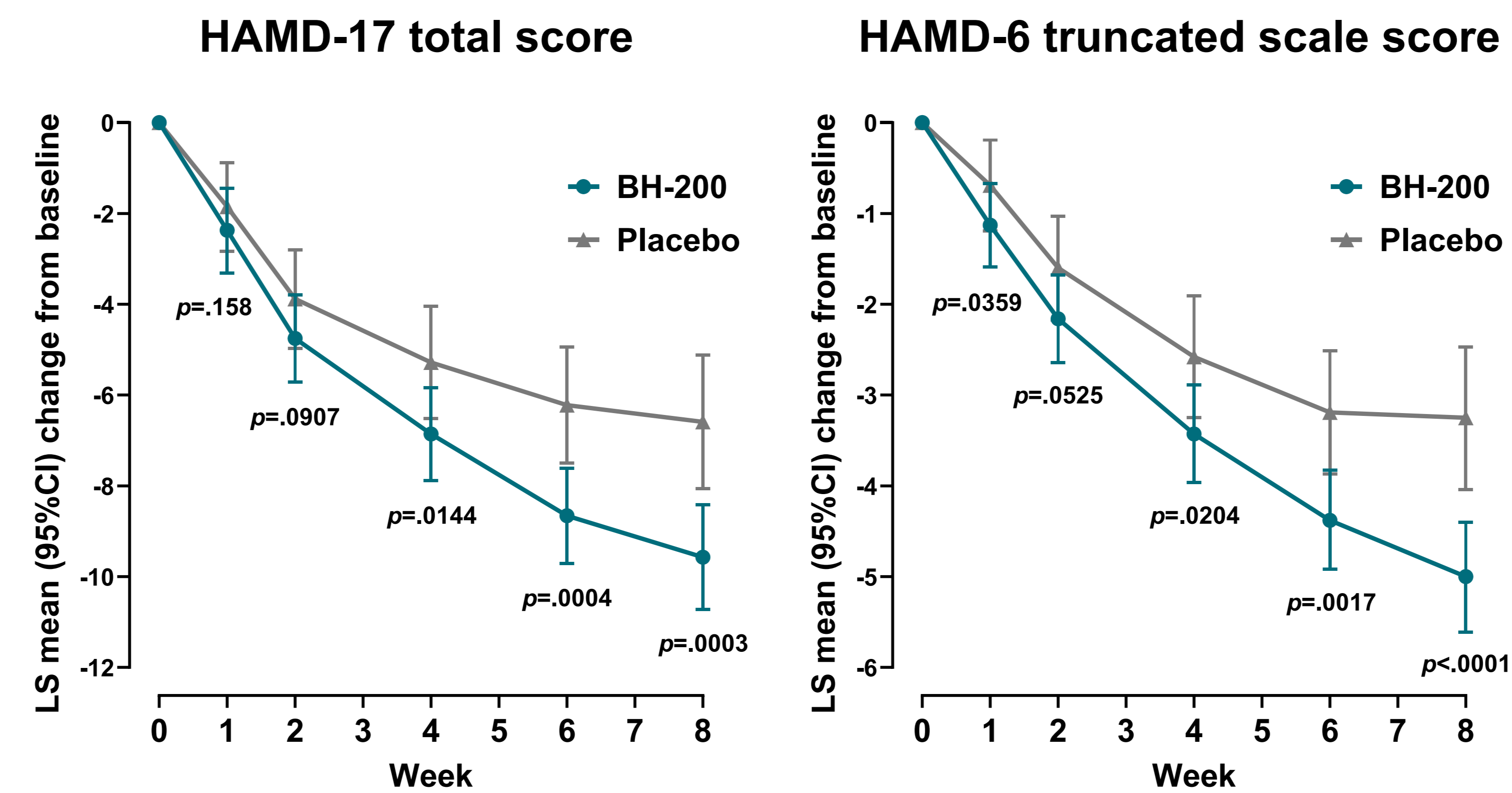
OLIVE (EudraCT: 2022-002757-26) was an 8-week, double-blind, randomized, placebo-controlled phase 2 trial in 338 adult MDD patients (331 in the modified intention-to-treat population, mITT), randomized 2:1 to BH-200 (250 mg BID) or placebo, performed across 50 sites in 8 countries.



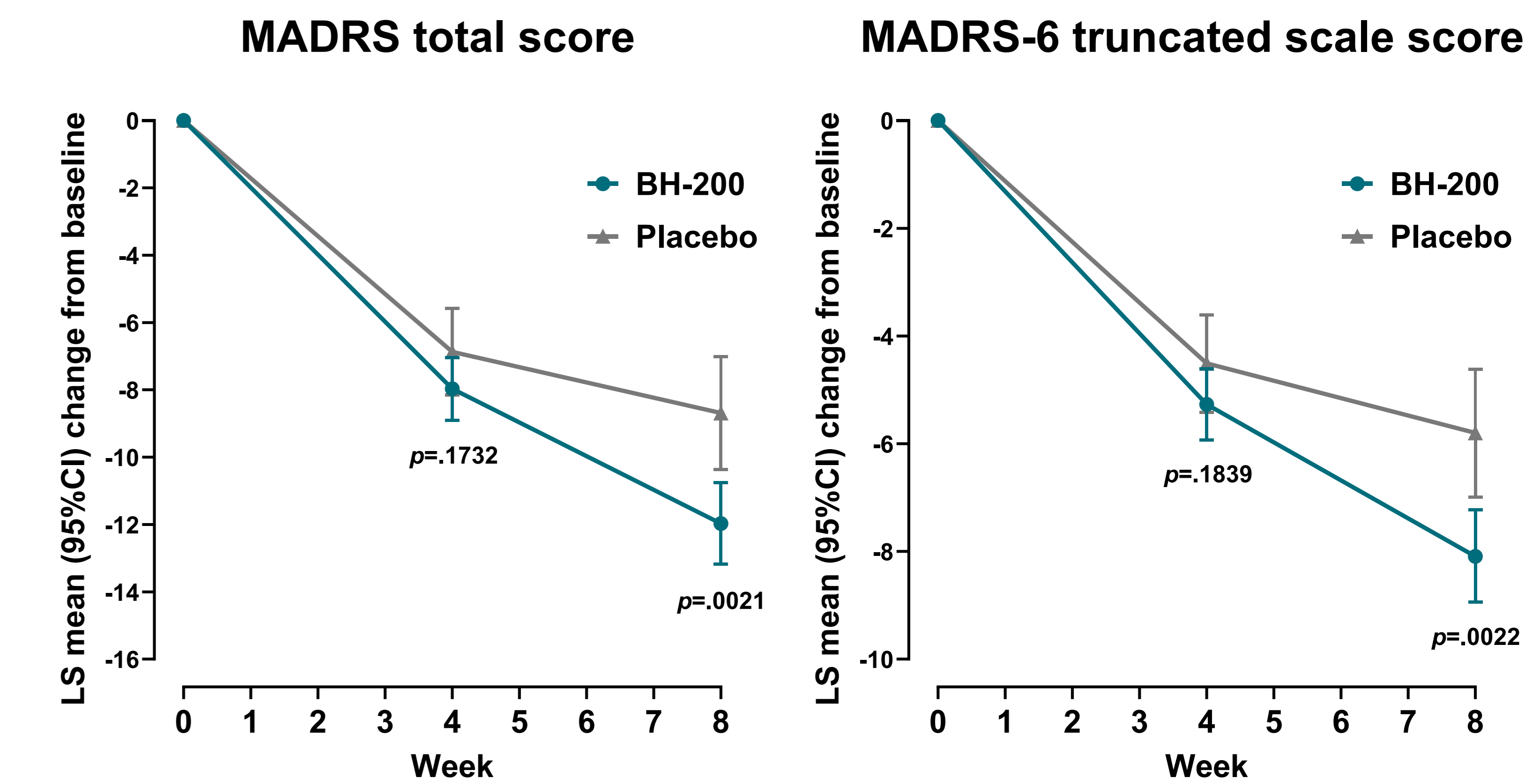
The primary endpoint was the change in the HAMD-17 total score from baseline to week 8 in a prespecified Subgroup C, defined by HPA-axis genetic classifier V1bPGS. The key secondary endpoint compared HAMD-17 between BH-200-treated patients in Subgroups C and A. Further secondary endpoints included changes in MADRS and other depression-related measures, quality-of-life and functioning scales, and BH-200 safety and tolerability profiles.

We have analyzed the change from baseline to week 8 using the full and truncated versions of HAMD and MADRS in the mITT population and conducted mixed models for repeated measures (MMRM). Cohen's d as a standardized effect measure is used to compare the features of the scales.

Results: HAMD



Results: MADRS



Among all patients receiving BH-200 and placebo, the change from baseline to week 8 was -9.57 and -6.59, respectively, for the HAMD-17 total score, -5 and -3.25, respectively, for the HAMD-6 truncated scale score, -11.97 and -8.69, respectively, for the MADRS total score, and -8.09 and -5.8, respectively, for the MADRS-6 truncated scale score.

Cohen's d	All patients	Subgroup A	Subgroup B	Subgroup C
HAMD-17 total score	0.44	0.55	0.49	0.28
HAMD-6 truncated scale score	0.46	0.61	0.47	0.33

Cohen's d	All patients	Subgroup A	Subgroup B	Subgroup C
MADRS total score	0.42	0.62	0.27	0.41
MADRS-6 truncated scale score	0.41	0.58	0.31	0.38

Cohen's standardized effect sizes for change from baseline at week 8 were 0.46 for HAMD-6 and 0.44 for HAMD-17, and 0.41 for MADRS-6 and 0.42 for the original 10-item MADRS in all patients; similar Cohen's standardized effect sizes for the full and truncated scales were also similar across the subgroups A, B, and C. The correlation between full and truncated scales was 0.75 for HAMD scales and 0.86 for MADRS scales in all patients.

References:

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