The Huntington’s Disease Health Index (HD-HI): Measuring Changes in Disease Burden in Response to Valbenazine During the KINETIC®-HD Trial

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ABSTRACT DESCRIPTION

In KINETIC-HD, adults with a diagnosis associated with Huntington’s disease (HD) received once-daily valbenazine (40-80 mg) for 12 weeks. An arm of the placebo-treated participants reported increased disease burden in the 4 weeks prior to screening. The HD-HI is a validated, disease-specific, patient-reported outcome (PRO) designed to measure clinically meaningful changes in HD-related burden in response to therapeutic interventions.

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RESULTS

Among participants with available HD-HI assessments at baseline (HI-GL), subscale scores in the valbenazine group were slightly higher (favorable) for mobility and hand/arm function and slightly lower (favorable) for emotional health, social satisfaction, cognition, fatigue, and depression (Table 2).

Among the 8 subscales with greater valbenazine improvements relative to placebo at Week 12, impact of pain was small (Table 2), but was reported with greater magnitude in the placebo group.

CONCLUSIONS

The trained evaluator HD-scw score was used to identify HD-related improvement meaningful changes in disease burden in response to therapeutic interventions.

The study’s greater reduction in HD-related disease burden was explained by valbenazine versus placebo in participants that are partially affected among patients experiencing chorea (heuristic movement), limb and arm function, mobility, and cognition.

Greater improvements with valbenazine relative to placebo were also found in domains related to emotional and social well-being, cognition, and gastrointestinal health/safety/swallowing.

These results indicate that the HD-HI was a valid and responsive measurement of patient-reported domains related to disease burden in the study population and could be used for capturing changes in future clinical trials of HD therapies.

REFERENCES

4MoCA total score, mean (SD)
5MoCA=mean (SD)
6UHDRS® Total Functional Capacity score ≥5 at screening, with score of 5−10 requiring repeat (≥37) in the baseline
7CGI-C
8Clinical Global Impression of Change
9Favors Valbenazine
10P=0.0379
11Favors Placebo
12P=0.0024
13Favors Placebo
14Mean change from baseline to Week 12
15Favors Placebo
16Mean change from baseline to Week 12
17Baseline-10 Week
18Baseline-12 Week
19Baseline-14 Week
20Baseline-16 Week
21Baseline-18 Week
22Baseline-20 Week
23Baseline-22 Week
24Baseline-24 Week
25Baseline-26 Week
26Baseline-28 Week
27Baseline-30 Week
28Baseline-32 Week
29Baseline-34 Week
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46Baseline-68 Week
47Baseline-70 Week
48Baseline-72 Week
49Baseline-74 Week
50Baseline-76 Week
51Baseline-78 Week
52Baseline-80 Week
53Baseline-82 Week
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