

Sustained Treatment Response With Long-Term Valbenazine in Patients With Tardive Dyskinesia

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Abstracts

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Abstract

Background. Valbenazine is a once-daily VMAT2 inhibitor approved for the treatment of tardive dyskinesia (TD), a persistent and potentially disabling movement disorder associated with prolonged exposure to antipsychotics, antiemetics, and other dopamine receptor blocking agents. The efficacy, safety, and tolerability of valbenazine has been established in several phase 3 trials, including a long-term study (KINECT 4 [NCT02405091]) in which participants received open-label valbenazine (40 or 80 mg) for 48 weeks. Post hoc analyses of KINECT 4 data were conducted to assess patterns of treatment response.

Methods. Data from KINECT 4 treatment completers (participants who reached the Week 48 visit and had the longest duration of treatment) were analyzed post hoc. TD was assessed using the Abnormal Involuntary Movement Scale (AIMS) total score (sum of items 1–7, as rated by the study investigator), the Clinical Global Impression of Change-Tardive Dyskinesia (CGI-TD), and the Patient Global Impression of Change (PGIC). Analyses were conducted at Week 8 (first study visit after the valbenazine dose-optimization period) and Week 48 using the following definitions of response: $\geq 50\%$ and $\geq 70\%$ improvement from baseline in AIMS total score; rating of “much improved” or “very much improved” (score ≤ 2) on the CGI-TD and PGIC.

Results. Of the 167 participants who entered KINECT 4, 103 (62%) were treatment completers and included for analysis. Of these 103 participants, 39% and 86% met the $\geq 50\%$ AIMS response threshold at Weeks 8 and 48, respectively. The percentages of participants who met the highly rigorous AIMS $\geq 70\%$ response threshold at Weeks 8 and 48 were 17% and 52%, respectively. Of the 40 participants with AIMS $\geq 50\%$ total score improvement at Week 8, 95% also met this threshold at Week 48 (“sustained response”). Of the 63 participants with $< 50\%$ AIMS improvement at Week 8, 81% achieved the $\geq 50\%$ response threshold by end of treatment at Week 48. The proportion of participants meeting the threshold for CGI-TD response also increased over time, from 50% at Week 8 to 92% at Week 48. PGIC results were similar, with response rates of 53% and 88% at Weeks 8 and 48, respectively.

Conclusions. Post hoc analyses of data from a 48-week, open-label study of once-daily valbenazine showed that the proportion of participants meeting rigorous treatment response thresholds increased over time. By the end of treatment at Week 48, $> 80\%$ of participants demonstrated robust improvements in TD, as assessed using the AIMS ($\geq 50\%$ improvement), CGI-TD (score ≤ 2), and PGIC (score ≤ 2).

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Assessing the Quality of a Telemental Health Training Initiative for Social Work Students to Reduce the Workforce Mental Health Crisis in the Child and Adolescent Population

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