(40% and 42%, respectively) compared to those who did not achieve early PGIC and CGI-TD improvement (39% and 38%, respectively).

CONCLUSIONS: Results from this long-term valbenazine trial indicate that many participants achieved at least minimal patient- and clinician-reported improvement at Week 2. AIMS outcomes at Week 48 demonstrated long-term reductions in TD severity regardless of early response. More research is needed to understand the association between early improvement and long-term treatment effects, but early non-improvement based on subjective measures may not be predictive of long-term treatment failure.

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140
Effects of Long-Term Valbenazine on Tardive Dyskinesia in KINECT 4: Post Hoc Response and Shift Analyses

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ABSTRACT: Study Objective: Valbenazine (VBZ) is a highly selective vesicular monoamine transporter 2 (VMAT2) inhibitor approved for the treatment of tardive dyskinesia (TD), a persistent and potentially disabling movement disorder associated with prolonged antipsychotic exposure. Post hoc response and shift analyses were conducted using Abnormal Involuntary Movement Scale (AIMS) data from KINECT 4 (NCT02405091), a long-term open-label study in which participants received up to 48 weeks of open-label treatment with once-daily VBZ (40 or 80 mg).

METHODS: KINECT 4 included participants who met the following criteria: ages 18 to 85 years; DSM-IV diagnosis of schizophrenia, schizoaffective disorder, or mood disorder; neuroleptic-induced TD for ≥3 months prior to screening; stable psychiatric status (Brief Psychiatric Rating Scale score <50); no high risk of active suicidal ideation or behavior. Stable doses of concomitant medications to treat psychiatric and medical disorders were allowed. VBZ dosing was initiated at 40 mg, with escalation to 80 mg at Week 4 based on clinical assessment of TD and tolerability; a dose reduction to 40 mg was allowed if 80 mg was not tolerated. AIMS responses, ranging from ≥10% to 100% improvement from baseline in AIMS total score (sum of items 1-7), were analyzed at Week 48 based on scoring by site investigators. AIMS shift, conducted for each item (representing 7 different body regions), was defined as an improvement from a score ≥3 (moderate/severe) at baseline to a score ≤2 (none/minimal/mild) at Week 48.

RESULTS: 103 participants had an available AIMS assessment at Week 48 (40 mg, n=20; 80 mg, n=83 [including 9 with a dose reduction]). At Week 48, 94.2% of participants had ≥30% total AIMS score improvement (40 mg, 90.0%; 80 mg, 95.2%) and 86.4% had ≥50% improvement (40 mg, 90.0%; 80 mg, 85.5%). The percentage of participants meeting the remaining AIMS response thresholds ranged from 9.7% (for 100% response) to 97.1% (for ≥10% response). In participants who had an AIMS item score ≥3 at baseline, shifts to a score ≤2 at Week 48 were as follows: 100% for lips, upper extremities, and lower extremities (VBZ 40 mg and 80 mg). Shift rates for the remaining regions were as follows (40 mg, 80 mg): face (100% [9/9], 96.9% [31/32]), jaw (100% [10/10], 97.6% [40/41]), tongue (100% [11/11], 97.9% [47/48]), trunk (87.5% [7/8], 88.9% [16/18]).

CONCLUSIONS: After 48 weeks of treatment with once-daily VBZ (40 or 80 mg), >85% of KINECT 4 participants had a clinically meaningful AIMS response (≥30% total score improvement), a robust AIMS response (≥50% total score improvement), or an AIMS shift (from item score ≥3 at baseline to score ≤2 at Week 48). These results suggest that VBZ is an appropriate long-term treatment for many adults with TD.
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141
Moderating Perspectives of Long Acting Injectable Use of Antipsychotics: A Literature Review

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