CONCLUSIONS: A clinician-based global assessment indicated ongoing, meaningful TD improvements in adults who received once-daily VBZ in the current study. In participants treated for >1 year, continued patient satisfaction rates with VBZ were high.
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Long-term Safety and Tolerability of Once-Daily Valbenazine in Patients with Tardive Dyskinesia

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ABSTRACT: Objective: To evaluate the long-term safety and tolerability of once-dailyvalbenazine in adults with tardive dyskinesia (TD).

METHODS: Data were pooled from KINECT 3 (NCT02274558: 6-week double-blind placebo-controlled period, followed by a 42-week double-blind extension and 4-week drug-free washout) and KINECT 4 (NCT02405091: 48-week open-label treatment period and 4-week drug-free washout). KINECT 3/4 study completers could enroll in a subsequent rollover study (NCT02736955: up to 72 weeks of open-label treatment or until valbenazine became commercial available); data from this study were described separately for this analysis. Valbenazine dose groups (40 and 80 mg) were pooled for analysis. Safety assessments included treatment-emergent adverse events (TEAEs) and the Columbia-Suicide Severity Rating Scale (C-SSRS). Psychiatric status was assessed in KINECT 3 and KINECT 4 using the following measures: Positive and Negative Syndrome Scale (PANSS) total score and Calgary Depression Scale for Schizophrenia (CDSS) in participants with schizophrenia/schizoaffective disorder; Montgomery-Åsberg Depression Rating Scale (MADRS) and Young Mania Rating Scale (YMRS) in participants with a mood disorder.

RESULTS: Analyses included 304 KINECT 3/4 participants and 160 rollover participants. In KINECT 3/4, the summary of TEAEs was as follows: any TEAE (71.7%), serious TEAE (16.8%), and discontinuation due to TEAE (15.5%). TEAEs reported in ≥5% of all KINECT 3/4 participants were headache (8.9%), urinary tract infection (8.9%), somnolence (7.9%), fatigue (6.3%), dizziness (5.9%), and suicidal ideation (5.6%). The summary of TEAEs from the rollover study was as follows: any TEAE (53.1%), serious TEAE (10.0%), and discontinuation due to TEAE (5.6%). The most common TEAEs in the rollover study were back pain and urinary tract infection (4.4%, each); no TEAE was reported in ≥5% of participants. Minimal changes in psychiatric status were observed in KINECT 3/4, as indicated by mean score changes from baseline to Week 48 in participants with schizophrenia/schizoaffective disorder (PANSS total, –3.2; CDSS total, –0.5) or a mood disorder (MADRS total, 0.3; YMRS total, –1.0). Over one-third of study participants had a lifetime history of suicidal ideation or behavior (KINECT 3/4, 41%; rollover, 38%). Most participants had no C-SSRS suicidal ideation at study baseline; of these, >90% had no emergence of suicidal ideation at any time during the study (KINECT 3/4, 93% [276/296]; rollover, 98% [153/156]).

CONCLUSIONS: Valbenazine was well tolerated and no unexpected safety signals were found in adults who received >1 year of once-daily treatment. Psychiatric stability was maintained, and few participants experienced any emergence of suicidal ideation during the studies despite 35–40% having a lifetime history of suicidality. These results indicate that once-daily valbenazine may be an appropriate treatment for the long-term management of TD.
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Pseudo Cranial Nerve I Dysfunction: Subjective Hyposmia and Subjective Hypogeusia but Normosmia and Normogeusia - 3 cases

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ABSTRACT: INTRODUCTION: Hyposmia refers to reduced ability to smell and hypogeusia is a partial loss