[3] Teva Pharmaceuticals, Frazer, Pennsylvania, USA
[4] University of South Florida Parkinson's Disease and Movement Disorders Center, Tampa, Florida, USA
[5] University of North Carolina School of Medicine, Chapel Hill, North Carolina, USA
[6] Baylor College of Medicine, Houston, Texas, USA
[7] Rocky Mountain Movement Disorders Center, Englewood, Colorado, USA
[8] University Clinical Center of Silesian Medical University, Katowice, Poland
[9] Medical College of Georgia, Augusta, Georgia, USA
[10] Cleveland Clinic, Cleveland, Ohio, USA

ABSTRACT: Background: Tardive dyskinesia (TD) is an often-irreversible movement disorder that may intensify the stigma of patients with psychiatric disorders and worsen quality of life. In two randomized, double-blind, placebo (PBO)-controlled, 12-week trials, ARM-TD and AIM-TD ('parent studies'), deutetrabenazine (DTB) demonstrated statistically significant improvements in centrally read Abnormal Involuntary Movement Scale (AIMS) scores at Week 12 compared with PBO and was generally well tolerated.

STUDY OBJECTIVE: To evaluate the long-term efficacy of DTB in an open-label safety study following double-blind treatment using site-rated efficacy measures: AIMS, the Clinical Global Impression of Change (CGIC) and the Patient Global Impression of Change (PGIC), which may be used in real-world clinical practice settings.

METHOD: Patients with TD who completed the parent studies were eligible to enter this open-label, long-term extension (OLE) after completing the 1-week washout period and final evaluation in the blinded portion of the trial. This extension comprised a 6-week titration period followed by a long-term maintenance phase. Patients began DTB at 12 mg/day, titrating up to a maximum total dose of 48 mg/day based on dyskinesia control and tolerability. Efficacy endpoints included in this analysis are the change in site-rated AIMS score (items 1–7) from parent study baseline, and the proportion of patients who were "Much Improved" or "Very Much Improved" (treatment success) on the CGIC and PGIC from OLE baseline.

RESULTS: At the end of the parent studies (Week 12), patients treated with DTB had experienced greater mean (standard error) improvements in site-rated AIMS score (–5.0 [0.40]) than patients given PBO (–3.2 [0.47]). With long-term DTB treatment, both groups experienced improvements in site-rated AIMS scores (prior DTB, –7.9 [0.62]; prior placebo, –6.6 [0.64]) compared with parent study baseline. Similarly, at the end of the parent studies, a greater proportion of patients treated with DTB had treatment success on the CGIC (DTB, 51%; PBO, 32%) and the PGIC (DTB, 46%; PBO: 33%); whereas at Week 54 of the OLE study, treatment success on CGIC and PGIC were similar in both the CGIC (prior DTB: 66%; prior PBO: 68%) and PGIC (prior DTB: 62%; prior PBO: 62%) groups. DTB was generally well tolerated.

CONCLUSIONS: Patients treated with DTB showed improvements in abnormal movements, as measured by site-rated AIMS, CGIC, and PGIC scores, which may be used in real-world clinical practice settings. These results corroborate the previously reported efficacy of DTB as observed in the 12-week, double-blind ARM-TD and AIM-TD trials, in which central raters were used to evaluate AIMS scores.
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Too Scared to Blink: Pseudoparkinsonism due to Nyctophobia

Khurram Janjua, MD[1]; and Alan R. Hirsch, MD[2]

[1] Smell and Taste Treatment and Research Foundation, Chicago, IL
[2] Medical Director, Smell and Taste Treatment and Research Foundation, Chicago, IL

ABSTRACT: Introduction: A hallmark of Parkinson's disease is facial akinesia with decrease in blink frequency (Karson, 1984). A markedly decreased blink frequency from nyctophobia, a fear of the dark, has not heretofore been reported.

METHOD: Case Study: A 26-year-old right handed male presented with a 20-year history of phantasmagoria. Visual hallucinations of strangers appeared several to a hundred times a day, seconds to minutes in duration. These morbid images were horrific, of dead people or ghosts, suddenly appearing in his visual space, actively attacking real people. Examples included a little girl, decapitated, cradling her head in her arm or Freddy Krueger like apparitions, shooting, stabbing, strangling or maiming actual people who were within the patient's visual field. He was able to differentiate between the hallucinations and real people, either from the context (a non hallucination would not be murdering someone else), or he would wait for the hallucinations to vanish, allowing him to then interact with the person who is actually there. The images were so disturbing to him that he fled his home state to run away from the hallucinations, but to his chagrin, they persisted. There were

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diurnal variations to his hallucinations, which were more frequent at night, or when he closed his eyes, and the fear of these has induced nyctophobia. In order to avoid these, he attempted to curtail closing his eyes or blinking. He had been treated with 9 different psychotropic medications, which had no effect on his hallucinations. Phenytoin was begun, and once therapeutic levels were achieved, all of his hallucinations resolved, as did his nyctophobia, with return to normal blink frequency.

RESULTS: Physical examination: Bilateral palmar erythema. Facial expression with decreased blink frequency, approximately 1/per minute, but not otherwise hypomimetic. Neurological examination: Cranial Nerve (CN) Examination: CN III, IV and VI: bilateral ptosis. Motor Examination: Normal tone without cogwheel rigidity. No bradykinesia. Drift Testing: Right upward-outward drift, right cerebellar spooning, and Abductor Digiti Minimi sign. Gait: Normal without instability or retropulsion. Reflexes: 1+ throughout. Hoffman Reflex: positive bilaterally. Other: Magnetic Resonance Imaging of brain with/without infusion: Normal. Five-day Electroencephalogram: Temporal Lobe Status Epilepticus with bilateral foci.

DISCUSSION: In this individual, the sheer terror of phantasmagoria with his eyes closed, forced him to maintain them in the open position as long as possible, reducing his blink frequency to once a minute or less. The return to a normal rate of blink frequency with treatment using phenytoin, with resolution of his horrific hallucinations, further validates this as the origin for his infrequent blinking. In those with low nictation, without other manifestations of Parkinson's disease, query as to volitional inhibition of blink frequency and nyctophobia is warranted.

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Global Improvement and Patient Satisfaction: Results from a Long-term, Open-label, Rollover Study of Valbenazine in Tardive Dyskinesia

Cherian Verghese, MD[1]; Jean-Pierre Lindenmayer, MD[2]; Stephen R. Marder, MD[3]; Joshua Burke, MS[4]; Roland Jimenez, BA[5]; Chuck Yonan, PharmD[6]; Khody Farahmand, PharmD[7]; and Scott Siegert, PharmD[8]

[1] Principal Investigator, Keystone Clinical Studies, LLC, Norristown, PA
[2] Clinical Professor, Department of Psychiatry, New York University School of Medicine, New York, NY
[3] Professor, Psychiatry and Biobehavioral Sciences, University of California Los Angeles, David Geffen School of Medicine, Los Angeles, CA
[4] Director, Biostatistics and Data Management, Neurocrine Biosciences, Inc., San Diego, CA
[5] Director, Clinical Programs, Neurocrine Biosciences, Inc., San Diego, CA
[6] Senior Director, HEOR, Neurocrine Biosciences, Inc., San Diego, CA
[7] Director, Medical Communications, Neurocrine Biosciences, Inc., San Diego, CA
[8] Executive Director, Medical Affairs, Neurocrine Biosciences, Inc., San Diego, CA

ABSTRACT: Objective: Valbenazine (VBZ) is a novel vesicular monoamine transporter 2 (VMAT2) inhibitor approved to treat tardive dyskinesia (TD) in adults. It has been evaluated in 2 long-term studies (KINECT 3, KINECT 4) in which participants received VBZ (40 or 80 mg) for up to 48 weeks. This long-term rollover study (NCT02736955) was conducted to evaluate global TD improvement and patient satisfaction with once-daily VBZ.

METHODS: Key eligibility criteria: age 18 to 85 years; completion of KINECT 3 or KINECT 4; maintenance medications (for schizophrenia, schizoaffective disorder, or mood disorder) at stable doses; Brief Psychiatric Rating Scale score <50; no significant risk of active suicidal ideation or behavior. Following washout of prior VBZ treatment (Weeks 48 to 52 of KINECT 3 and KINECT 4), participants were re-initiated at 40 mg (4 weeks) and escalated to 80 mg based on tolerability and clinical assessment of TD; dose was reduced to 40 mg if 80 mg was not tolerated (80/40 mg). If unable to tolerate the 40 mg dose, the participant was discontinued. Participants received open-label VBZ for up to 72 weeks or until commercial availability. Assessments included Clinical Global Impression of Severity-TD (CGIS-TD: range, 1 ["normal, not at all ill"] to 7 ["among the most extremely ill patient"]) and Patient Satisfaction Questionnaire (PSQ: range, 1 ["very satisfied"] to 5 ["very dissatisfied"]).

RESULTS: 160 participants with available data were included in analyses (40 mg =35; 80 mg =117; 80/40 mg =8); 138 were receiving treatment when VBZ became commercially available. The percentages of participants who completed visits at Wks 12, 24, 36, and 48 were 96.3%, 78.1%, 56.9% and 35.0%, respectively. Few reached Wk 60 (n=4) or Wk 72 (n=0) due to commercial availability. The percentage of participants with CGIS-TD score ≤2 ("normal, not at all ill" or "borderline ill") increased from baseline (before restarting VBZ) (40mg, 5.7%; 80mg, 18.1%) to Wk 48 (40 mg , 41.7%; 80 mg , 74.4%). At baseline, almost all participants rated their prior VBZ experience with a PSQ score ≤2 ("very satisfied" or "somewhat satisfied") (40 mg , 100%, 80 mg , 99.1%). Similar results were seen at the Wk 48 visit, with most participants continuing to express satisfaction with VBZ (40 mg , 100%; 80 mg , 97.4%).

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