46 Confirmed Safety of Deutetrabenazine for Tardive Dyskinesia in a 2-Year Open-label Extension Study

Hubert H. Fernandez, MD1; David Stamler, MD2; Mat D. Davis, PhD3; Stewart A. Factor, DO4; Robert A. Hauser, MD, MBA5; Joohi Jimenez-Shahed, MD6; William G. Ondo, MD7; L. Fredrik Jarskog, MD8; Scott W. Woods, MD9; Mark S. LeDoux, MD, PhD10; David R. Shprecher, DO, MS11; and Karen E. Anderson, MD12

1 Cleveland Clinic, Center for Neurological Restoration, Cleveland, Ohio, USA
2 Teva Pharmaceuticals, La Jolla, California, USA
3 Teva Pharmaceuticals, Frazer, Pennsylvania, USA
4 Emory University, Atlanta, Georgia, USA
5 University of South Florida Parkinson’s Disease and Movement Disorders Center, Tampa, Florida, USA
6 Baylor College of Medicine, Houston, Texas, USA
7 Methodist Neurological Institute, Houston, Texas, USA; Weill Cornell Medical College, New York, New York, USA
8 University of North Carolina School of Medicine, Chapel Hill, North Carolina, USA
9 Yale School of Medicine, New Haven, Connecticut, USA
10 University of Tennessee Health Science Center, Memphis, Tennessee, USA
11 University of Utah, Salt Lake City, Utah, USA; Banner Sun Health Research Institute, Sun City, Arizona, USA
12 Georgetown University, Washington, District of Columbia, USA

ABSTRACT: Study Objective: To evaluate the long-term safety and tolerability of deutetrabenazine in patients with tardive dyskinesia (TD) at 2 years.

BACKGROUND: In the 12-week ARM-TD and AIM-TD studies, deutetrabenazine showed clinically significant improvements in Abnormal Involuntary Movement Scale scores compared with placebo, and there were low rates of overall adverse events (AEs) and discontinuations associated with deutetrabenazine.

METHOD: Patients who completed ARM-TD or AIM-TD were included in this open-label, single-arm extension study, in which all patients restarted/started deutetrabenazine 12 mg/day, titrating up to a maximum total daily dose of 48 mg/day based on dyskinesia control and tolerability. The study comprised a 6-week titration period and a long-term maintenance phase. Safety measures included incidence of AEs, serious AEs (SAEs), and AEs leading to withdrawal, dose reduction, or dose suspension. Exposure-adjusted incidence rates (EAIRs; incidence/patient-years) were used to compare AE frequencies for long-term treatment with those for short-term treatment (ARM-TD and AIM-TD). This analysis reports results up to 2 years (Week 106).

RESULTS: 343 patients were enrolled (111 patients received placebo in the parent study and 232 received deutetrabenazine). There were 331.4 patient-years of exposure in this analysis. Through Week 106, EAIRs of AEs were comparable to or lower than those observed with short-term deutetrabenazine and placebo, including AEs of interest (akathisia/restlessness [long-term EAIR: 0.02; short-term EAIR range: 0–0.25], anxiety [0.09; 0.13–0.21], depression [0.09; 0.04–0.13], diarrhea [0.06; 0.06–0.34], parkinsonism [0.01; 0–0.08], somnolence/sedation [0.09; 0.06–0.81], and suicidality [0.02; 0–0.13]). The frequency of SAEs (EAIR 0.15) was similar to those observed with short-term placebo (0.33) and deutetrabenazine (range 0.06–0.33) treatment. AEs leading to withdrawal (0.08), dose reduction (0.17), and dose suspension (0.06) were uncommon.

CONCLUSIONS: These results confirm the safety outcomes seen in the ARM-TD and AIM-TD parent studies, demonstrating that deutetrabenazine is well tolerated for long-term use in TD patients.

Presented at: American Academy of Neurology Annual Meeting: April 21–27, 2018, Los Angeles, California, USA
Funding Acknowledgements: Funding: This study was supported by Teva Pharmaceuticals, Petach Tikva, Israel

47 Sustained Functional Recovery and Symptom Remission After Maintenance Treatment with Aripiprazole Once-Monthly for Patients with Bipolar I Disorder

Eduard Vieta, MD1; Ross A. Baker, PhD2; Jessica J. Madera, MD3; Peter Zhang, PhD3; Pedro Such, MD4; Maxine Chen, PhD5; and Joseph Calabrese, MD6

1 Chair, Department of Psychiatry and Psychology, Hospital Clinic, Bipolar Unit, Institute of Neuroscience, University of Barcelona, IDIBAPS, CIBERSAM, Barcelona, Catalonia, Spain
2 Director, Global Medical Affairs, Otsuka Pharmaceutical Development & Commercialization, Inc., Princeton, NJ, USA