severity-score ≤4 in the Positive and Negative Syndrome Scale total score were observed in 16.7% (aripiprazole), 21.2% (olanzapine), 35.1% (PP1M), 27.3% (quetiapine), and 37.2% (risperidone) of patients. The patients showed significant improvements involving safety features as they experienced significant overall weight loss (p = 0.0001) and prolactine decrease (risperidone p = 0.0001, paliperidone extended-release p = 0.0001). AOM once-monthly was well tolerated, presenting no new safety signals. Patient also reported an overall significant improvement on their quality of life measured with the Quality of Life Rating Scale (QLS) (p = 0.0004) as well as in sexual functioning PRSexDQ-SALSEX (p = 0.0001). In addition, the all cause treatment discontinuation rate after6-month follow-up was small (n = 3; 5,55%)

CONCLUSIONS: These data illustrate that stable, non-acute but symptomatic patients either on oral antipsychotic therapy or under monthly antipsychotic treatment may show clinically meaningful improvement of psychotic symptoms, tolerability involving relevant side effects and quality of life perception. The findings are limited by the naturalistic study design; thus, further studies are required to confirm the current findings.

Keywords: Long-acting injectable antipsychotic therapy. Oral antipsychotic. Effectiveness- Tolerability-Quality of life.

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Long-term Treatment with Deutetrabenazine Is Associated with Continued Improvement in Tardive Dyskinesia: Results from an Open-label Extension Study

Robert A. Hauser, MD, MBA[1]; Hubert H. Fernandez, MD[2]; David Stamler, MD[3]; Mat D. Davis, PhD[4]; Stewart A. Factor, DO[5]; Joohi Jimenez-Shahed, MD[6]; William G. Ondo, MD[7]; L. Fredrik Jarskog, MD[8]; Scott W. Woods, MD[9]; Mark S. LeDoux, MD, PhD[10]; David R. Shprecher, DO, MS[11]; and Karen E. Anderson, MD[12]

[1] University of South Florida Parkinson's Disease and Movement Disorders Center, Tampa, Florida, USA
[2] Cleveland Clinic, Center for Neurological Restoration, Cleveland, Ohio, USA
[3] Teva Pharmaceuticals, La Jolla, California, USA
[4] Teva Pharmaceuticals, Frazer, Pennsylvania, USA
[5] Emory University, Atlanta, Georgia, 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 long-term efficacy of deutetrabenazine in patients with tardive dyskinesia (TD) by examining response rates from baseline in Abnormal Involuntary Movement Scale (AIMS) scores. Preliminary results of the responder analysis are reported in this analysis.

BACKGROUND: In the 12-week ARM-TD and AIM-TD studies, the odds of response to deutetrabenazine treatment were higher than the odds of response to placebo at all response levels, and there were low rates of overall adverse events and discontinuations associated with deutetrabenazine.

METHOD: Patients with TD 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 and a long-term maintenance phase. The cumulative proportion of AIMS responders from baseline was assessed. Response was defined as a percent improvement from baseline for each patient from 10% to 90% in 10% increments. AIMS score was assessed by local site ratings for this analysis.

RESULTS: 343 patients enrolled in the extension study (111 patients received placebo in the parent study and 232 patients received deutetrabenazine). At Week 54 (n = 145; total daily dose [mean ± standard error]: 38.1 ± 0.9 mg), 63% of patients receiving deutetrabenazine achieved ≥30% response, 48% of patients achieved ≥50% response, and 26% achieved ≥70% response. At Week 80 (n = 66; total daily dose: 38.6 ± 1.1 mg), 76% of patients achieved ≥30% response, 59% of patients achieved ≥50% response, and 36% achieved ≥70% response. Treatment was generally well tolerated.

CONCLUSIONS: Patients who received long-term treatment with deutetrabenazine achieved response rates higher than those observed in positive short-term studies, indicating clinically meaningful long-term treatment benefit.

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

Hubert H. Fernandez, MD[1]; David Stamler, MD[2]; Mat D. Davis, PhD[3]; Stewart A. Factor, DO[4]; Robert A. Hauser, MD, MBA[5]; Joohi Jimenez-Shahed, MD[6]; William G. Ondo, MD[7]; L. Fredrik Jarskog, MD[8]; Scott W. Woods, MD[9]; Mark S. LeDoux, MD, PhD[10]; David R. Shprecher, DO, MS[11]; and Karen E. Anderson, MD[12]

[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.

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

Eduard Vieta, MD[1]; Ross A. Baker, PhD[2]; Jessica J. Madera, MD[3]; Peter Zhang, PhD[4]; Pedro Such, MD[5]; Maxine Chen, PhD[6]; and Joseph Calabrese, MD[7]

[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