Abstract

Introduction. Deutetrabenazine is FDA-approved for the treatment of tardive dyskinesia (TD) in adults. In two 12-week pivotal trials (ARM-TD/AIM-TD), deutetrabenazine significantly improved Abnormal Involuntary Movement Scale (AIMS) scores and was well-tolerated. This post hoc analysis examined the efficacy and safety of long-term deutetrabenazine treatment in TD patients with comorbid psychiatric illness, including schizophrenia/schizoaffective disorder and mood disorders (bipolar/depression/other).

Methods. Patients who completed ARM-TD or AIM-TD enrolled in the 3-year, open-label extension (OLE) study. Deutetrabenazine was titrated based on dyskinesia control and tolerability. Change from baseline in total motor AIMS score, Patient Global Impression of Change (PGIC), Clinical Global Impression of Change (CGIC), and adverse events (AEs) were analyzed in subgroups by comorbid psychiatric illness.

Results. A total of 337 patients in the OLE study were included in the analysis: 205 patients with schizophrenia/schizoaffective disorder (mean age, 55 years; 50% male; 6.4 years since diagnosis; 92% taking DRA) and 131 patients with mood disorders (mean age, 60 years; 35% male; 4.6 years since diagnosis; 50% taking DRA). At week 145, mean ± SE dose was 40.4 ± 1.1 mg/day for schizophrenia/schizoaffective disorder (n = 88) and 38.5 ± 1.2 mg/day for mood disorders (n = 72). Mean ± SE change from baseline in AIMS score at week 145 was −6.3 ± 0.49 and −7.1 ± 0.58, 56% and 72% achieved PGIC treatment success, and 66% and 82% achieved CGIC treatment success in schizophrenia/schizoaffective disorder and mood disorder patients, respectively. Overall AE incidence (exposure-adjusted incidence rates [incidence/patient-years]) was low: any, 1.02 and 1.71; serious, 0.10 and 0.12; leading to discontinuation, 0.07 and 0.05).

Conclusion. Long-term deutetrabenazine treatment provided clinically meaningful improvements in TD-related movements, with a favorable safety profile, regardless of underlying comorbid psychiatric illness.

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Long-Term Efficacy and Safety of Deutetrabenazine in Patients with Tardive Dyskinesia by Concomitant Dopamine-Receptor Antagonist Use

Robert A. Hauser, MD, MBA[1], Hadas Barkay, PhD[2], Hubert H. Fernandez, MD[3], Stewart A. Factor, DO[4], Joohi Jimenez-Shahed, MD[5], Nicholas Gross, MS[6], Leslie Marinelli, BS[6], Amanda Wilhelm, PhD[6], Mark Forrest Gordon, MD[6], Juha-Matti Savola, MD, PhD[7] and Karen E. Anderson, MD[8]

[1]University of South Florida Parkinsons Disease and Movement Disorders Center, Tampa, FL, USA, [2]Teva Pharmaceuticals, Netanya, Israel, [3]Cleveland Clinic, Cleveland, OH, USA, [4]Emory University, Atlanta, GA, USA, [5]Icahn School of Medicine at Mount Sinai, New York, NY, USA, [6]Teva Pharmaceuticals, West Chester, PA, USA, [7]Teva Pharmaceuticals, Basel, Switzerland, and [8]Georgetown University, Washington, DC, USA

Abstract

Introduction. Tardive dyskinesia (TD) is an involuntary movement disorder that can result from exposure to dopamine-receptor antagonists (DRAs). Deutetrabenazine demonstrated significant improvements in Abnormal Involuntary Movement Scale (AIMS) scores in the 12-week pivotal trials (ARM-TD/AIM-TD). This post hoc analysis assessed the long-term efficacy and safety of deutetrabenazine by baseline DRA use.

Methods. Patients who completed ARM-TD or AIM-TD enrolled in the 3-year, open-label extension (OLE) study, with deutetrabenazine dose titrated based on dyskinesia control and tolerability. Change from baseline in total motor AIMS score, Patient Global Impression of Change (PGIC), Clinical Global Impression of Change (CGIC), and adverse event (AE) rates were analyzed in subgroups by baseline DRA use.

Results. Of 337 patients in the OLE study, 254 were taking DRAs at baseline (mean age, 56 years; 48% male; 6.0 years since diagnosis) and 83 were not (mean age, 60 years; 31% male; 4.9 years since diagnosis). Mean ± SE dose at week 145 was 39.9 ± 1.0 mg/day in patients taking DRAs (n = 108) and 38.5 ± 1.5 mg/day in patients not taking DRAs (n = 53). At week 145, mean ± SE change from baseline in AIMS score was −6.1 ± 0.43 and −7.5 ± 0.71; 64% and 62% achieved PGIC treatment success; and 69% and 81% achieved CGIC treatment success, respectively. Overall AE incidence was low (exposure-adjusted incidence rates [incidence/patient-years]: any, 1.08 and 1.97; serious, 0.10 and 0.12; leading to discontinuation, 0.06 and 0.05).

Conclusion. This analysis suggests that deutetrabenazine for long-term treatment of TD is beneficial, with a favorable safety profile, regardless of concomitant DRA use.

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Effect of REL-1017 (Esmethadone) on Cholesterol, Triglycerides, PCSK9, and hs-CRP in a Phase 2a Double-Blind Randomized Trial in Patients with MDD

Nicola Ferri, PhD[1], Marco Pappagallo, MD[2,3], Sheetal Patel, MD, MS[2], Franco Folli, MD, PhD[4], Sara De Martin, PharmD[5], Maria Giovanna Lupo, PhD[5], Sergio Traversa[2] and Paolo L. Manfredi, MD[2]

[1]Department of Medicine, University of Padova, Padova, Italy, [2]Relmada Therapeutics, New York, NY, USA, [3]Department of Anesthesiology, Albert Einstein College of Medicine, Bronx, NY, USA, [4]Department of Health Science, University of Milano, Milano, Italy, and [5]Department of Pharmaceutical and Pharmacological Sciences, University of Padova, Padova, Italy

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