Long-Term Treatment With Deutetrabenazine Is Associated With Continued Improvement in Tardive Dyskinesia (TD): Results From an Open-Label Extension Study

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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. Updated results of the responder analysis are reported here.

Background:
In the 12-week ARM-TD and AIM-TD studies, the percentage of patients achieving ≥50% and ≥70% response was higher in the deutetrabenazine-treated group than the percentage of patients in the placebo group, and there were low rates of overall adverse events and discontinuations associated with deutetrabenazine.

Design/Methods: 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 or 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 (ongoing through Week 158). The cumulative proportion of AIMS responders from baseline was assessed; response rates for at least 50% and 70% improvement from baseline for each patient were evaluated. AIMS score was assessed by local site raters for this analysis.

Results: 343 patients enrolled in the extension study. At Week 54 (n=250; total daily dose [mean ± standard error]: 38.6±0.66 mg), 48% of patients achieved ≥50% response and 24% achieved ≥70% response. At Week 106 (n=169; total daily dose: 39.6±0.77 mg), 55% of patients achieved ≥50% response, and 30% achieved ≥70% response. At Week 145, (n=77; total daily dose: 39.2±1.12 mg), 74% of patients achieved ≥50% response and 52% achieved ≥70% response. Treatment was generally well tolerated. Exposure-adjusted incidence rates (EAIRs) of common AEs were headache (0.04), somnolence (0.06), anxiety (0.07), and depression (0.05).

Conclusions: Patients who received long-term treatment with deutetrabenazine achieved response rates that were indicative of clinically meaningful long-term treatment benefit.