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

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

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