Deutetrabenazine demonstrated efficacy and favorable safety and tolerability after 12 weeks of treatment—response was assessed based on achieving a ≥50% or ≥70% improvement in Abnormal Involuntary Movement Scale (AIMS) score from baseline of the OL extension study (C-20) after completing a 1-week washout. To evaluate the long-term efficacy and safety of deutetrabenazine in patients with TD from an interim analysis of data from the ongoing C-20 study, a pooled, post-hoc safety and efficacy analysis of patients who took ≥1 dose of the study drug through Week 54, 106, or 132 of treatment was conducted. Patients were directly rolled over into the OL extension study (C-20) after completing a 1-week washout. The response rates achieved with deutetrabenazine in treating TD are presented at 54, 106, and 132 weeks in Figure 6. AIMS, Abnormal Involuntary Movement Scale; CGIC, Clinical Global Impression of Change; DRA, dopamine-receptor antagonist; OL, open-label; SE, standard error.

**METHODS**

**Study Design**

Patients were directly rolled over into the OL extension study (C-20) following completion of a 1-week washout and a 72% of Week 15 responders who reached Week 106 were responders at Week 15 (n=250). Safety Summary (Table 2) shows the most common AEs in the OL extension study were depression, anxiety, and constipation. When adjusted for exposure, study discontinuations, dose reductions, and dose suspensions due to AEs were calculated. In the OL extension study, serious AEs were experienced by 60 patients (9.6%). The response rates increased from Week 15 to Week 54, and CGIC responder rates increased from Week 15 to Week 106. CGIC responder rates were consistent among completers at Weeks 54, 106, and 132, suggesting that the improvements in AIMS scores over time were not due to dropout of patients with worse AIMS scores. Table 1 presents baseline characteristics of patients in the OL extension study. AIMS scores were assessed by local site raters. AEs were analyzed using a mixed-effects model with a random intercept and a fixed factor of week. AEs leading to dose suspension were uncommon. The response rates achieved with deutetrabenazine in treating TD are presented at 54, 106, and 132 weeks in Figure 6. AIMS, Abnormal Involuntary Movement Scale; CGIC, Clinical Global Impression of Change; DRA, dopamine-receptor antagonist; OL, open-label; SE, standard error.

**RESULTS**

**Patients**

Demographics and baseline characteristics are shown in Table 1. Key patient characteristics were consistent over time (Figure 2). AIMS scores were comparable to or lower than those observed with short-term deutetrabenazine treatment and placebo. The most common AEs in the OL extension study were depression, anxiety, and constipation. When adjusted for exposure, study discontinuations, dose reductions, and dose suspensions due to AEs were calculated. In the OL extension study, serious AEs were experienced by 60 patients (9.6%). The response rates increased from Week 15 to Week 54, and CGIC responder rates increased from Week 15 to Week 106. CGIC responder rates were consistent among completers at Weeks 54, 106, and 132, suggesting that the improvements in AIMS scores over time were not due to dropout of patients with worse AIMS scores. Table 1 presents baseline characteristics of patients in the OL extension study. AIMS scores were assessed by local site raters. AEs were analyzed using a mixed-effects model with a random intercept and a fixed factor of week. AEs leading to dose suspension were uncommon. The response rates achieved with deutetrabenazine in treating TD are presented at 54, 106, and 132 weeks in Figure 6. AIMS, Abnormal Involuntary Movement Scale; CGIC, Clinical Global Impression of Change; DRA, dopamine-receptor antagonist; OL, open-label; SE, standard error.

**Efficacy Outcomes**

Mean AIMS scores decreased from baseline over time for patients remaining in the study (Figure 4). Figure 3 shows the total daily dose among completers of Week 54, 106, or 132. Open-label; SE, standard error. AIMS scores were assessed by local site raters. AEs were analyzed using a mixed-effects model with a random intercept and a fixed factor of week. AEs leading to dose suspension were uncommon. The response rates achieved with deutetrabenazine in treating TD are presented at 54, 106, and 132 weeks in Figure 6. AIMS, Abnormal Involuntary Movement Scale; CGIC, Clinical Global Impression of Change; DRA, dopamine-receptor antagonist; OL, open-label; SE, standard error.

**REFERENCES**

3. Bo Choi, PhD (MedErgy), with funding from Teva Pharmaceuticals.