Development of Deutetrabenazine as a Potential New Non-Antipsychotic Treatment for Tourette Syndrome in Children and Adolescents

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ABSTRACT: Background: Tourette syndrome (TS) is a neurodevelopmental disorder characterized by the superimposition of motor and phonic tics. 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 (EIRs; incidence/patient-years) were used for calculating AE frequencies. This analysis reports results up to Week 158.

RESULTS: A total of 343 patients were enrolled (111 received placebo and 232 received deutetrabenazine in the parent studies). At the time of this analysis, 183 patients were still receiving treatment: 259 completed 1 year, 172 completed 2 years, and 41 completed 3 years. There were 623 patient-years of exposure. More than 40% of patients reached the maximum dose. EIRs of AEs were comparable to or lower than those observed in the ARM-TD and AIM-TD short-term randomized trials of deutetrabenazine vs. placebo. The frequency of SAEs (EIR 0.10) was similar to that observed with short-term placebo (0.33) and short-term deutetrabenazine (range 0.06–0.33) treatment. AEs leading to withdrawal (0.06), dose reduction (0.10), and dose suspension (0.05) were uncommon.

CONCLUSION: These results support the safety outcomes observed in the ARM-TD and AIM-TD parent studies and the safety of deutetrabenazine for long-term use in patients with TD.

Funding Acknowledgements: This study was funded by Teva Pharmaceuticals, Petach Tikva, Israel

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ABSTRACTS 207