ABSTRACT DESCRIPTION

Older patients taking a dopamine-receptor blocking agent have an increased risk of tardive dyskinesia (TD), a persistent and potentially disabling movement disorder. These analyses, therefore, being the first to assess the effects of an approved TD medication in elderly patients (≥65 years), indicate that long-term once-daily valbenazine is appropriate for this population.

INTRODUCTION

TD is a persistent and potentially disabling movement disorder associated with prolonged exposure to antipsychotics and other dopamine-receptor blocking agents (DRBAs).

Compared to younger adults, older adults (≥65 years) have a higher risk of developing TD after a shorter duration of DRBA treatment.

Valbenazine is a highly selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is the only approved TD medication with once-daily dosing and enough clinical trial data to specifically indicate no required dose adjustments in elderly patients (≥65 years).

To date, no results have been reported to the effects of VMAT2 inhibitors on TD in elderly patients using the more conventional threshold of 65 years.

Therefore, data from two long-term trials of valbenazine were analyzed post hoc to evaluate treatment outcomes in elderly study participants (≥65 years) versus a younger cohort (<65 years).

OBJECTIVES

Undertake the increased risk for TD in elderly patients taking antipsychotics or other DRBAs.

Describe the results from the first analyses to assess the effects of an approved medication (valbenazine) on TD in elderly patients (≥65 years).

Apply the substantial and clinically meaningful improvements found in this analysis to the real-world management of TD in elderly patients.

METHODS

STUDY DESIGN

Participants in KINETIC 3 and KINETIC 4 received up to 48 weeks of once-daily treatment with valbenazine 40 or 80 mg (Figure 5).

All valbenazine dose groups were pooled for the analysis, participants who initially received placebo in KINETIC 3 were excluded.

RESULTS

Demographics and baseline characteristics are presented in Table 1.

Both subgroups had high rates of clinician- and patient-reported improvement (CGTD and PGIC) and PCSS scores at Week 48, which trended in the same direction (Figures 4 and 5).

High rates of clinically meaningful AIMS response (≥50% total score improvement) and the more robust, protocol-defined AIMS response (≥50% total score improvement) were found at Week 48, with no statistically significant differences between age subgroups (Figure 3).

Statistical analyses generally indicated no statistically significant differences between age subgroups in overall TEAEs (<65 years, 71.5%; ≥65 years, 72.7%) or serious TEAEs (<65 years, 16.5%; ≥65 years, 18.2%). However, discontinuations due to TEAEs were more common in elderly patients (<65 years, 15.3%; ≥65 years, 25.5%; P=0.05).

CONCLUSIONS

These analyses, based on data pooled from 2 large term studies, are the first to assess the effects of an approved TD medication in an elderly study population (≥65 years), and results indicate that TD treatment with once-daily valbenazine is appropriate and beneficial for this age group.

In both age subgroups (≥65 years, <65 years), substantial and clinically meaningful improvements in TD were found after 48 weeks of once-daily valbenazine treatment.

No statistically significant differences between age subgroups were found for overall TEAEs (<65 years, 71.5%; ≥65 years, 72.7%) or serious TEAEs (<65 years, 16.5%; ≥65 years, 18.2%); however, discontinuations due to TEAEs were more common in elderly patients (<65 years, 15.3%; ≥65 years, 25.5%; P=0.05).

REFERENCES

1. Case Western Reserve University School of Medicine, Cleveland, OH; University Hospitals of Cleveland Medical Center, Cleveland, OH; Neurocrine Biosciences, Inc., San Diego, CA.

Once-Daily Valbenazine Is Effective for Tardive Dyskinesia in Elderly Patients (≥65 Years)

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Figure 1. Study Design

Figure 2. AIMS Total Score Change from Baseline to Week 48 by Age Subgroup

Figure 3. AIMS Response Rates at Week 48 by Age Subgroup

Figure 4. CGI-TD Response Rates at Week 48 by Age Subgroup

Figure 5. PGIC Response Rates at Week 48 by Age Subgroup