

are allowed. Efficacy outcomes, analyzed by study visit, include mean changes from baseline in Unified Huntington's Disease Rating Scale (UHDRS[®]) Total Maximal Chorea (TMC) score and response status for Clinical Global Impression of Change (CGI-C) and Patient Global Impression of Change (PGI-C). Responders are defined as participants with a score ≤ 2 (rating of "much improved" or better). Efficacy outcomes up to Week 50 (~1 year) are reported. Treatment-emergent adverse events (TEAEs) are presented for all participants who received ≥ 1 dose of study drug, regardless of time in study (2 to 104 weeks). All interim outcomes were analyzed descriptively.

Results. Of 127 participants enrolled at the time of analysis, 98 (77.2%) had completed KINECT-HD and 29 (22.8%) were newly enrolled. Of 125 participants who received treatment, 65 (52.0%) were female and 118 (94.4%) were white; mean age (\pm SD) was 54.8 (\pm 11.5) years. A mean reduction in TMC score was observed by Week 2 with valbenazine 40 mg (-3.4 [\pm 3.1], n=118); mean reductions were sustained from Week 8 (5.6 [\pm 3.6], n=110) to Week 50 (-5.8 [\pm 4.1], n=66) (all valbenazine doses). At Week 50, 76.9% (50/65) of participants met the pre-defined threshold for CGI-C response; 74.2% (49/66) met the threshold for PGI-C response. Analyses in participants taking concomitant antipsychotic medications are ongoing and will be presented at the meeting. Of the 125 participants who received treatment, 119 (95.2%) reported at least 1 TEAE and 17 (13.6%) discontinued due to a TEAE. The most commonly reported TEAEs were falls (30.4%), fatigue (24.0%), and somnolence (24.0%).

Conclusions. Interim TMC data from KINECT-HD2 indicated chorea improvement with once-daily valbenazine by Week 2 (3.4 [\pm 3.1] with 40 mg), similar to KINECT-HD Week 2 results (-2.9 [\pm 3.0]). The interim analyses also indicated that long-term treatment with valbenazine was well tolerated and provided clinically meaningful improvement in chorea severity for up to ~1 year.

Funding. Neurocrine Biosciences, Inc.

paucity of data regarding the course of TD in patients no longer taking antipsychotics, a meta-analysis of 3 long-term valbenazine studies was conducted in subgroups with and without concomitant antipsychotic use at baseline.

Methods. KINECTTM-3 (NCT02274558), KINECTTM-4 (NCT02405091), and JKINECT (NCT03176771) data were analyzed in study completers taking antipsychotics at baseline (AP+) and those who were not (AP-). The Abnormal Involuntary Movement Scale (AIMS) total score was used to measure TD severity at baseline, Wk48 (end of valbenazine treatment), and Wk52 (4 weeks after valbenazine withdrawal). The meta-analysis implemented a random-effects model that weighted each study based on inverse variance, adjusted for between-study variance.

Results. Of 576 enrolled patients, 336 (58.3%) were study completers and included for analysis: AP+ (n=269); AP- (n=67). Mean baseline AIMS scores ranged from 7.9–14.9 (AP+) and 10.9–14.5 (AP-). Mean changes from baseline in AIMS scores indicated substantial TD improvements with valbenazine at Wk48 (AP+, 6.1; AP-, -6.5) and return towards baseline severity at Wk52 (AP+, -2.1; AP-, -1.4).

Conclusions. Once-daily valbenazine treatment resulted in substantial and sustained TD improvement through Wk48, with no meaningful differences between AP+ and AP- subgroups. The return towards baseline severity after valbenazine withdrawal shows TD is chronic and often irreversible, even in patients no longer taking antipsychotics. Continuous treatment with valbenazine may be warranted irrespective of antipsychotic therapy.

Funding. Neurocrine Biosciences, Inc.

Valbenazine Improves Tardive Dyskinesia with or Without Concomitant Antipsychotic Therapy: A Meta-Analysis of Three Long-Term Valbenazine Trials

Eduardo Dunayevich, MD¹, Stephen R. Marder, MD², Sean C. Hinton³, Stewart A. Factor, DO⁴, Yumi Watanabe⁵ and Arline Nakanishi, MS¹

¹Neurocrine Biosciences, Inc., San Diego, CA, USA; ²Department of Psychiatry and Behavioral Science, UCLA David Geffen School of Medicine, Los Angeles, CA, USA; ³Neurocrine Biosciences, Inc., San Diego, CA, USA; ⁴Department of Neurology, Emory University School of Medicine, Atlanta, GA, USA and ⁵Mitsubishi Tanabe Pharma Corporation, Osaka, Japan

Introduction. Valbenazine is a highly selective vesicular monoamine transporter 2 inhibitor indicated for tardive dyskinesia (TD), a persistent and potentially debilitating movement disorder associated with prolonged antipsychotic exposure. Given the

Correlates of Psychiatric Polypharmacy Among Child and Adolescent Psychiatric Inpatients

Sean Lynch, MD, Timothy Becker, MD, Parul Shanker, MD, Paige Staudenmaier, MD, Dalton Martin, LCSW, Alicia Leong, BA and Timothy Rice, MD

Background. Rates of psychiatric illness among the child and adolescent population have increased over the past several decades. As social and government agencies work to expand access to mental health treatment, more and more children and adolescents are receiving medications for their symptoms. However, many drugs used in this population are not approved for people under the age of 18, and have not been studied in terms of long-term impact on the developing brain. A significant proportion of these patients receive psychiatric polypharmacy, or the prescription of 2 or more psychotropic agents. This rate has increased from about 8% in 1996 to over 40% in 2005. Factors correlated with polypharmacy include older age, male gender, White race, and low socioeconomic status. Polypharmacy can increase the risk of drug-drug interactions, increase morbidity/mortality through cumulative toxicity, and cause decreased medication adherence.

Study Aims: This study aimed to examine psychiatric polypharmacy specifically among psychiatrically hospitalized patients