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The Effects of Concomitant Anticholinergic Use on Tardive Dyskinesia

Thank you for contacting Neurocrine Biosciences with your unsolicited Medical Information request regarding INGREZZA® (valbenazine) capsules and the effect of concomitant anticholinergic use on tardive dyskinesia (TD) outcomes.

INGREZZA is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia.[1]

Data were pooled from two long-term valbenazine clinical trials (2 Phase 3 studies: KINECT 3 Long-term Extension [NCT02274558] and KINECT 4 [NCT02405091]) to evaluate the effect of anticholinergic use on TD outcomes. During the study, participants were allowed to remain on stable doses of concomitant antipsychotic medications to treat psychiatric disorders. The mean change from baseline to Week 48 in the Abnormal Involuntary Movement Scale (AIMS) total score was used to evaluate TD improvement. Interpretation of this post-hoc analysis may be limited due to small sample size.[2]

The pooled population (n=304) included 109 (35.9%) participants (80 mg, n=68; 40 mg, n=41) who were taking an anticholinergic and 195 (64.1%) participants who were not taking an anticholinergic at baseline. Of the participants who were taking an anticholinergic, 93% (101/109) were taking benztropine, which accounted for 33.2% (101/304) of the total pooled population. At Week 48, the mean changes in AIMS total score from baseline in participants who were taking an anticholinergic were -7.7 (n=35) and -2.9 (n=17) for the 80 mg and 40 mg groups, respectively. For participants who did not use an anticholinergic, the changes in AIMS total score from baseline to Week 48 were -8.8 (n=90) and -6.9 (n=37) for the 80 mg and 40 mg groups, respectively. At Week 52 (after 4-week washout), mean AIMS scores generally reverted towards baseline levels.[2]

Adverse reactions in the three placebo-controlled studies of 6-week duration reported at an incidence of >2% and greater than placebo were somnolence (10.9% and 4.2%, respectively), anticholinergic effects (5.4% and 4.9%), balance disorders/falls (4.1% and 2.2%), headache (3.4% and 2.7%,), akathisia (2.7% and 0.5%), vomiting (2.6% and 0.6%), nausea (2.3% and 2.1%) and arthralgia (2.3% and 0.5%), for valbenazine and placebo, respectively.[1]

For a more complete description of this analysis, please see attached data presentation from the 2018 Annual US Psychiatric and Mental Health Congress by Kane JM et al.

This letter and the enclosed material are provided in response to your unsolicited medical information inquiry. Please feel free to contact Neurocrine Medical Information at (877) 641-3461 or medinfo@neurocrine.com if you would like to request additional information.

References:

1. INGREZZA [package insert]. Neurocrine Biosciences, Inc., San Diego, CA.
2. Kane JM et al. Effects of concomitant medication use on tardive dyskinesia outcomes in long-term valbenazine trials. Poster presented at the 2018 Annual US Psychiatric and Mental Health Congress, Orlando, FL

Enclosures:

1. INGREZZA [package insert]. Neurocrine Biosciences, Inc., San Diego, CA.
2. Kane JM et al. Effects of concomitant medication use on tardive dyskinesia outcomes in long-term valbenazine trials. Poster presented at the 2018 Annual US Psychiatric and Mental Health Congress, Orlando, FL

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