



12780 El Camino Real, San Diego, CA 92130 (858) 617-7600

Thank you for contacting Neurocrine Biosciences for your unsolicited Medical Information request regarding INGREZZA® (valbenazine) capsules and the effect of baseline severity of tardive dyskinesia (TD) on TD response.

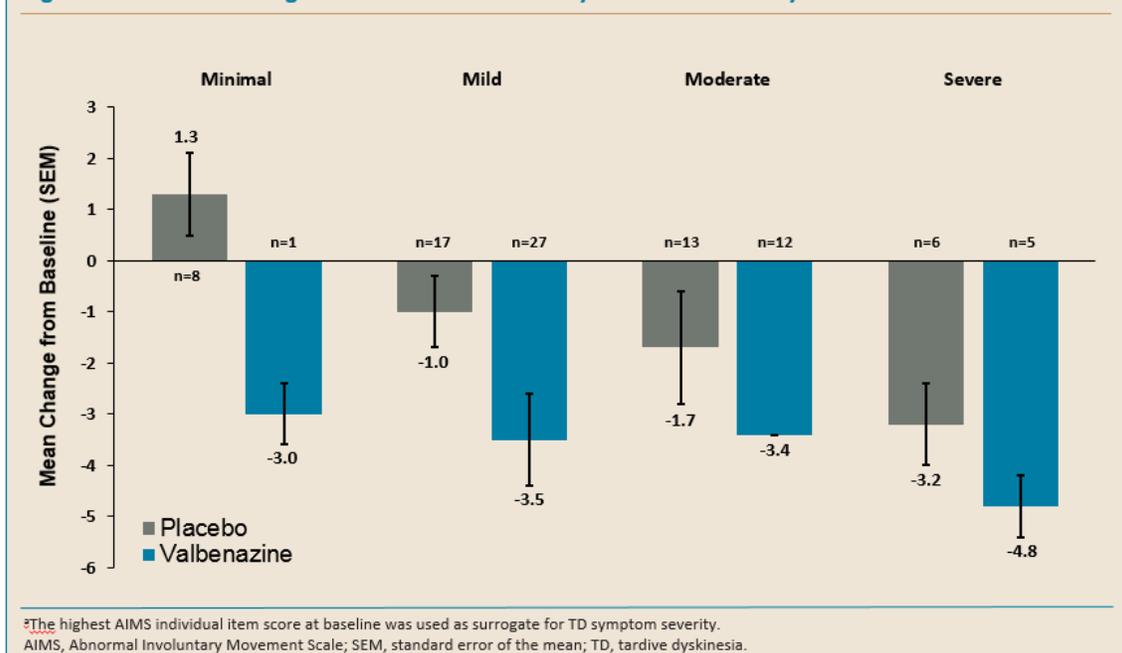
INGREZZA is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia.

KINECT 2 (NCT01733121) was a randomized, double-blind, parallel-group, placebo-controlled, Phase 2 clinical trial in moderate to severe TD patients with underlying schizophrenia, schizoaffective disorder, mood disorder (including bipolar disorder and major depressive disorder), or gastrointestinal disorder. Subjects (n=102) were randomized (1:1) to valbenazine (VBZ) (25-75 mg) or placebo administered once daily for six weeks. The primary endpoint was change-from-baseline (CFB) in the Abnormal Involuntary Movement Scale (AIMS) total dyskinesia score (items 1-7) at Week 6, assessed by central video raters blinded to treatment arm and study visit sequence.¹

Using the KINECT 2 population, CFB in AIMS scores (VBZ vs. placebo) were further explored by baseline TD severity. All subjects had qualitative assessment of moderate or severe TD at screening to meet the inclusion criteria, but given the variable nature of TD some subjects had mild or minimal TD at baseline assessment.

After six weeks of VBZ therapy, the ITT population showed a greater reduction of mean AIMS score compared to placebo across all baseline TD severity groups (severe: VBZ -4.8, placebo -3.2; moderate: VBZ -3.4, placebo -1.7; mild: VBZ -3.5, placebo -1.0; minimal: VBZ -3.0, placebo 1.3) (see Figure 1). Inferential statistical analyses were not performed.¹

Figure 1. AIMS Score Change from Baseline to Week 6 by Baseline TD Severity^a



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.



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Reference

1. Josiassen RC, Remington G, Burke J et al. (2016, May). Valbenazine (NBI-98854) is Effective for Treating Tardive Dyskinesia in Individuals with Schizophrenia or Mood Disorder. Presented at the 2016 annual meeting of the American Psychiatric Association, Atlanta, Georgia.

Enclosures

1. INGREZZA [package insert]. Neurocrine Biosciences, Inc., San Diego, CA; 2017.
2. Important Safety Information. Neurocrine Biosciences, Inc., San Diego, CA; 2017.