

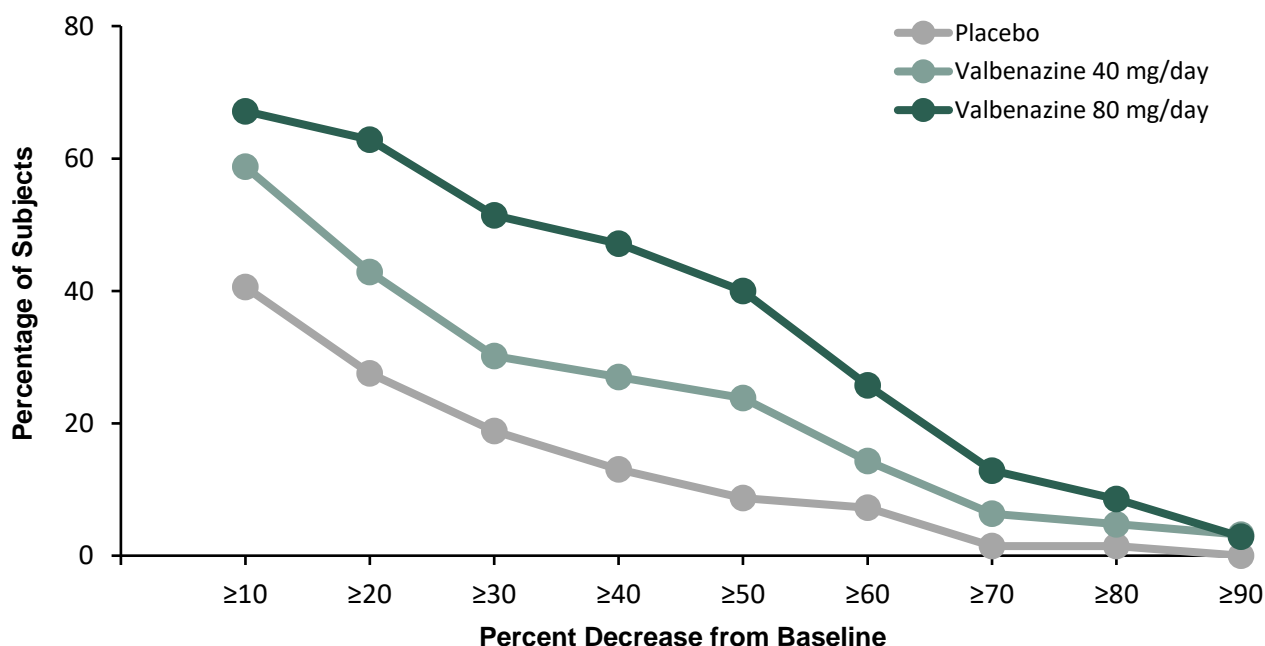
Participants not Responding to INGREZZA® (valbenazine) Capsules (“Non-Responders”) in the Tardive Dyskinesia (TD) Clinical Development Program

Thank you for contacting Neurocrine Biosciences with your unsolicited Medical Information request regarding the percentage of participants defined as not responding to INGREZZA® (valbenazine) capsules (“non-responders”) in the TD clinical development program.

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

There is no formal definition of response in tardive dyskinesia as the clinical presentation of the condition is variable, with severity and impact differing for each patient. In lieu of a “non-responder analysis,” **Figure 1** (below) demonstrates the cumulative percentages of participants, by study arm, who achieved certain thresholds of TD reduction in the double-blind, placebo-controlled portion of the pivotal KINECT 3 study as measured by the Abnormal Involuntary Movement Scale (AIMS) total score.²

Figure 1: AIMS Cumulative Response at Week 6 (ITT Population)



AIMS, Abnormal Involuntary Movement Scale; ITT, intent-to-treat.

The safety of valbenazine was evaluated in 3 placebo-controlled studies, each 6 weeks in duration including a total of 445 participants. During the three studies, the adverse reactions reported at >2% and >placebo were somnolence (somnolence, fatigue, sedation) (10.9% vs. 4.2%), anticholinergic effects (dry mouth, constipation, disturbance in attention, vision blurred, urinary retention) (5.4% vs. 4.9%), balance disorders/fall (4.1% vs. 2.2%), headache (3.4% vs. 2.7%), akathisia (2.7% vs. 0.5%), vomiting (2.6% vs. 0.6%), nausea (2.3% vs. 2.1%) and arthralgia (2.3% vs. 0.5%) for the INGREZZA and placebo groups, respectively.¹

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]. San Diego, CA: Neurocrine Biosciences, Inc.
2. Hauser RA, et.al. KINECT 3: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial of Valbenazine for Tardive Dyskinesia. American Journal of Psychiatry. 2017; 174(5):476-84. doi:10.1176/appi.ajp.2017.16091037 (<https://www.ncbi.nlm.nih.gov/pubmed/28320223>).

Enclosures:

- A. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.