

## Discontinuation of INGREZZA® (valbenazine) capsules

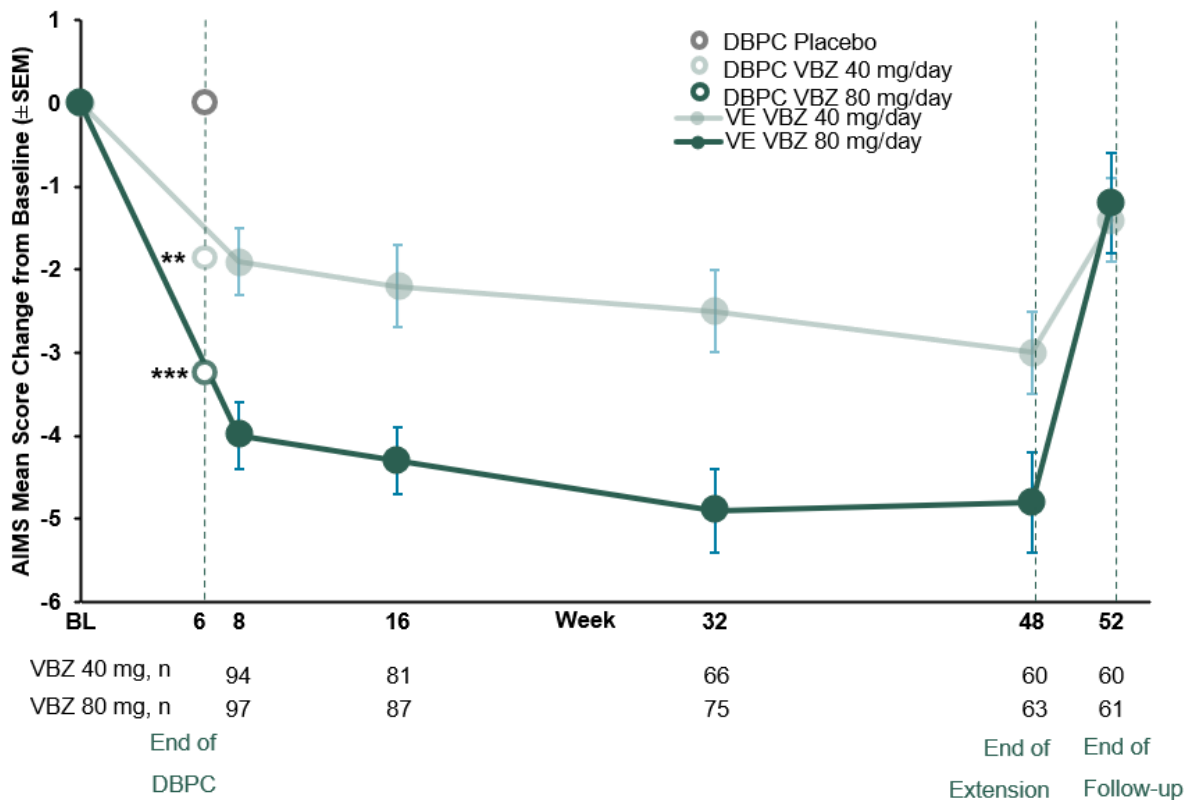
Thank you for contacting Neurocrine Biosciences with your unsolicited Medical Information request regarding discontinuation of INGREZZA.

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

There are no requirements in the INGREZZA FDA-approved full prescribing information for titration when discontinuing INGREZZA.

In the KINECT 3 study, participants demonstrated sustained reductions in TD severity (as measured by the mean change in abnormal involuntary movement scale [AIMS] total dyskinesia score) through 48 weeks of treatment (**Figure 1**). Following discontinuation of valbenazine treatment (participants were taken off drug from Weeks 48-52), the mean AIMS dyskinesia total scores returned towards baseline levels.<sup>1,2</sup>

**Figure 1:** AIMS Score Mean Change by Study Visit (ITT Population)



At end of DBPC: \*\*P<0.01; \*\*\*P<0.001 vs. placebo (statistical significance met for 80 mg/day based on the predefined fixed-sequence testing procedure); results based on least squares mean change from DBPC baseline using a mixed-effects model for repeated measures.

VE and drug-free follow-up periods: results based on arithmetic mean changes, with no imputation for missing values or significance testing between dose groups.

AIMS, Abnormal Involuntary Movement Scale; BL, baseline; DBPC, double-blind placebo-controlled; ITT, intent-to-treat; SEM, standard error of the mean; VBZ, valbenazine; VE, valbenazine extension.

**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](mailto:medinfo@neurocrine.com) if you would like to request additional information.**

**References:**

1. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.
2. Factor SA, et al. The Effects of Valbenazine in Participants with Tardive Dyskinesia: Results of the 1-Year KINECT 3 Extension Study. *Journal of Clinical Psychiatry*. 2017; 78(9):1344-50 (<https://www.ncbi.nlm.nih.gov/pubmed/29141124>).

**Enclosures:**

- A. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.
- B. Factor SA, et al. The Effects of Valbenazine in Participants with Tardive Dyskinesia: Results of the 1-Year KINECT 3 Extension Study. *Journal of Clinical Psychiatry*. 2017; 78(9):1344-50 (<https://www.ncbi.nlm.nih.gov/pubmed/29141124>).