

may be a prodromal syndrome which may act as a biological marker of dietary vitamin deficiency.

BMS is highly prevalent in postmenopausal women, wherein trigeminal nerve sensitivity may amplify and worsen pain, given a decrease in estrogen and progesterone [Martin 2007], indirectly influencing her BMS pain. Salivary output and composition can alter due to a drop in estrogen and progesterone as well, allowing baseline reduction of proprioceptive input on the tongue. Ergo, acting through Melzack and Wall's Gate Control Theory of Pain to disinhibit small C-fibers, it may be perceived as burning pain [Melzack 1965]. Given this case, in those who undergo abdominal surgery or hyperalimentation, query regarding BMS symptoms is warranted.

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### The Effects of Valbenazine on Tardive Dyskinesia: Subgroup Analyses of 3 Randomized, Double-Blind, Placebo-Controlled Trials

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**ABSTRACT:** Study Objectives: The approval of valbenazine (INGREZZA; VBZ) for the treatment of tardive dyskinesia (TD) in adults was based on results from double-blind, placebo (PBO)-controlled trials. These studies demonstrated the efficacy of once-daily VBZ based on intent-to-treat analyses. However, because many different types of patients can develop TD, subgroup analyses describing treatment outcomes by various patient factors were also conducted.

**METHODS:** Data were pooled from three 6-week trials: KINECT (NCT01688037), KINECT 2 (NCT01733121), KINECT 3 (NCT02274558), with outcomes analyzed by VBZ dose (80 mg, 40 mg) and PBO. Descriptive analyses conducted using the Abnormal Involuntary Movement Scale (AIMS) total score included: mean change from

baseline to Week 6; and AIMS response, defined as 50% improvement from baseline to Week 6. Subgroups were defined as follows: age (<55 years, ≥55 years), sex (male, female), psychiatric diagnosis (schizophrenia/schizoaffective disorder, mood disorder), CYP2D6 genotype (poor metabolizer [PM], non-PM), body mass index (BMI) (<18.5, 18.5 to <25, 25 to <30, ≥30 kg/m<sup>2</sup>), concomitant antipsychotic (yes, no); type of antipsychotic (atypical, typical/both); lifetime history of suicidality (yes, no); concomitant anticholinergic (yes, no); TD duration (<7 years, ≥7 years).

**RESULTS:** The pooled population included 373 participants (VBZ 80 mg, n = 101; VBZ 40 mg, n = 114; PBO, n = 158). Mean improvements from baseline to Week 6 in AIMS total score were greater overall with VBZ compared to PBO. Within subgroup categories, AIMS score improvement with VBZ 80 mg (recommended dose) was greater in CYP2D6 PMs (n = 17; 80 mg, -6.8; 40 mg, 2.4; PBO, 0.5), participants taking no concomitant antipsychotics (n = 64; 80 mg, -4.9; 40 mg, -3.0; PBO, 0.0), and overweight participants (BMI 25 to <30 kg/m<sup>2</sup>, n = 115; 80 mg, -4.2; 40 mg, 2.7; PBO, -0.7). Overweight participants also had the highest AIMS response rates at Week 6 (80 mg, 57.7%; 40 mg, 31.6%; PBO, 11.8%), followed by participants taking typical/both antipsychotics (n = 67; 80 mg, 57.1%; 40 mg, 20.0%; PBO, 25.0%), and those taking anticholinergics (n = 126; 80 mg, 52.9%; 40 mg, 22.7%; PBO, 6.3%).

**CONCLUSION:** These preliminary analyses indicate that TD improvements were generally greater with VBZ than PBO across most subgroups. However, the small sizes of some subgroups may need to be considered when interpreting results. Additional analyses within subgroup categories are ongoing and will be presented at the meeting.

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### The Burden of Tardive Dyskinesia Secondary to Antipsychotic Medication Use Among Patients With Mental Disorders

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**ABSTRACT:** Introduction: Extrapyramidal symptoms (EPS), including tardive dyskinesia (TD), may result