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Metabolic Parameters of INGREZZA® (valbenazine) capsules in Adults with Tardive Dyskinesia

Thank you for contacting Neurocrine Biosciences with your unsolicited Medical Information request regarding the potential for INGREZZA to affect metabolic parameters in adults with tardive dyskinesia (TD).

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

Metabolic data were pooled from three 6-week, randomized, double-blind, placebo-controlled trials (2 Phase 2 and 1 Phase 3): KINECT (NCT01688037), KINECT 2 (NCT01733121), KINECT 3 (NCT02274558). Treatment-emergent adverse events (TEAEs) and mean changes from baseline to Week 6 in body weight and laboratory values (glucose, cholesterol, triglycerides) were analyzed descriptively.[2]

The pooled safety population included 400 participants (40mg, n=110; 80mg, n=112; placebo, n=178), 84.0% of whom were taking ≥1 concomitant antipsychotic medication. Metabolic-related TEAEs occurred in less than 2% in all treatment groups (**Table 1**). For body weight and laboratory parameters, mean changes from baseline to Week 6 were small and not clinically relevant: body weight, kg (40mg, 0.2; 80mg, 0.4; placebo, 0.2); glucose, mg/dL (40mg, 3.2; 80mg, 3.2; placebo, -4.5); cholesterol, mg/dL (40mg, 3.9; 80mg, 3.7; placebo, -0.4); and triglycerides, mg/dL (40mg, 1.2; 80mg, -8.1; placebo, -5.8). In addition, no potentially clinically significant changes in cholesterol, glucose, or triglycerides were reported during the 6-week double-blind treatment period.[2]

Table 1: Treatment-Emergent Adverse Events

	Placebo (n=178)	Valbenazine 40 mg (n=110)	Valbenazine 80 mg (n=112)
Any TEAE, n (%)	71 (39.9)	48 (43.6)	53 (47.3)
Potentially metabolic TEAEs, n (%)[a]			
Decreased appetite	2 (1.1)	2 (1.8)	2 (1.8)
Increased appetite	1 (0.6)	1 (0.9)	2 (1.8)
Weight increased	1 (0.6)	1 (0.9)	2 (1.8)
Blood glucose increased	0	1 (0.9)	2 (1.8)
Glycosylated hemoglobin increased	1 (0.6)	0	1 (0.9)
Glucose urine present	0	0	1 (0.9)
Blood triglycerides increased	0	0	1 (0.9)
Glycosylated hemoglobin increased	1 (0.6)	0	1 (0.9)
Diabetes mellitus inadequate control	1 (0.6)	0	0
Abnormal loss of weight	1 (0.6)	0	0
Glycosuria	1 (0.6)	0	0
Hypoglycemia	1 (0.6)	0	0

[a]Reported in any participant
TEAE, treatment-emergent adverse event

For a complete description of these analyses, please see the attached data presentation from the 2017 Psych Congress annual meeting by McIntyre RS, et al.

NEUROCRINE® BIOSCIENCES

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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. McIntyre RS, et al. Effects of once-daily valbenazine on metabolic parameters in adults with tardive dyskinesia. Poster presented at the Pysch Congress; September 16-19, 2017; New Orleans, LA.

Enclosures:

A. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.
B. McIntyre RS, et al. Effects of once-daily valbenazine on metabolic parameters in adults with tardive dyskinesia. Poster presented at the Pysch Congress; September 16-19, 2017; New Orleans, LA.