KINECT-DCP: Clinical Trial Overview

A Phase 3, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of valbenazine for the treatment of dyskinesia due to cerebral palsy

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The information contained in these slides relates to a use of valbenazine that has not been approved by the FDA or any other regulatory agency

FDA, United States Food and Drug Administration

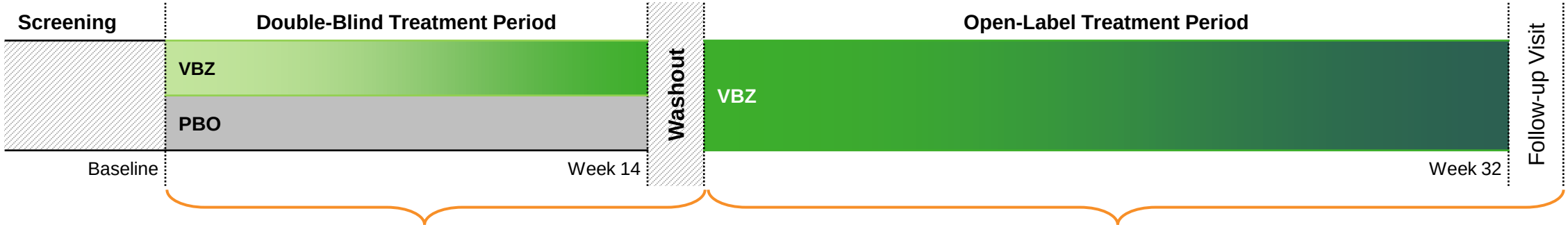
KINECT-DCP: Study Design[1,2]

A Phase 3, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of valbenazine for the treatment of dyskinesia due to cerebral palsy

Valbenazine has not been approved by the FDA for the treatment of dyskinesia due to cerebral palsy

Study Details (NCT05206513)

~80 participants will be enrolled; randomized 1:1



- 14-week treatment period
- Patients randomized 1:1 PBO to VBZ

- 32-week treatment period
- All patients receive VBZ

VBZ capsule administered once daily orally or via gastrostomy tube

PBO, placebo; VBZ, valbenazine

1. Clinicaltrials.gov. Accessed March 11, 2023. https://clinicaltrials.gov/ct2/show/NCT05206513?term=NCT05206513&draw=2&rank=1 | 2. Data on File (VBZ-DCP-0002). Neurocrine Biosciences.

KINECT-DCP: Inclusion & Exclusion Criteria

Key Inclusion Criteria

- Male or female 6 to 70 years old
- Medically confirmed diagnosis of dyskinetic cerebral palsy (DCP): cerebral palsy with choreiform movements (i.e., a hyperkinetic movement disorder due to cerebral palsy)
- Medical conditions are stable and expected to remain stable throughout the study

Key Exclusion Criteria

- Are pregnant or breastfeeding
- Have a clinical diagnosis or history of dyskinesia due to condition other than cerebral palsy
- Have inability to swallow soft solids, unless medications can be administered via a gastrostomy tube
- Have any suicidal behavior or suicidal ideation in the year prior to screening or on Day 1
- Is a substance abuser of any compound
- Known history of long QT syndrome or cardiac tachyarrhythmia, or clinically significant ECG abnormalities

DCP, dyskinetic cerebral palsy; ECG, electrocardiogram

Clinicaltrials.gov. Accessed March 11, 2023. https://clinicaltrials.gov/ct2/show/NCT05206513?term=NCT05206513&draw=2&rank=1

KINECT-DCP: Assessments

Primary Efficacy Endpoint

- Change in the Total Maximal Chorea (**TMC**) score of the Unified Huntington Disease Rating Scale (UHDRS) from baseline to the average of the Week 12 and Week 14 assessments

Key Secondary Endpoints

- Change in Clinical Global Impression of Severity (**CGI-S**) score from baseline to Week 14
- Change in the Movement Disorders - Childhood Rating Scale (**MD-CRS**) Part I score from baseline to Week 14
- Change in the Total Maximal Dystonia (**TMD**) score of the UHDRS from baseline to the average of the Week 12 and Week 14 assessments
- Patient, Caregiver, and Clinical Global Impression of Improvement (**PGI-I, CaGI-I, and CGI-I**) score at Week 14
- Goal attainment score using the Goal Attainment Scale (**GAS**) at Week 14
- Change in pain assessment from baseline to Week 14 using the Faces Pain Scale-Revised (**FPS-R**)
- Change in the UHDRS Total Motor Score (**TMS**) from baseline to the average of the Week 12 and Week 14 assessments

Safety Endpoints

- Safety assessments and monitoring will occur throughout the trial

Clinicaltrials.gov. Accessed March 11, 2023. https://clinicaltrials.gov/ct2/show/NCT05206513?term=NCT05206513&draw=2&rank=1