NBI-98854-ATS3019: Clinical Trial Overview

NEUROCRINE® BIOSCIENCES

The use of valbenazine as adjunctive treatment in schizophrenia is investigational and not approved by the FDA

The FDA has approved valbenazine for the treatment of adults with tardive dyskinesia

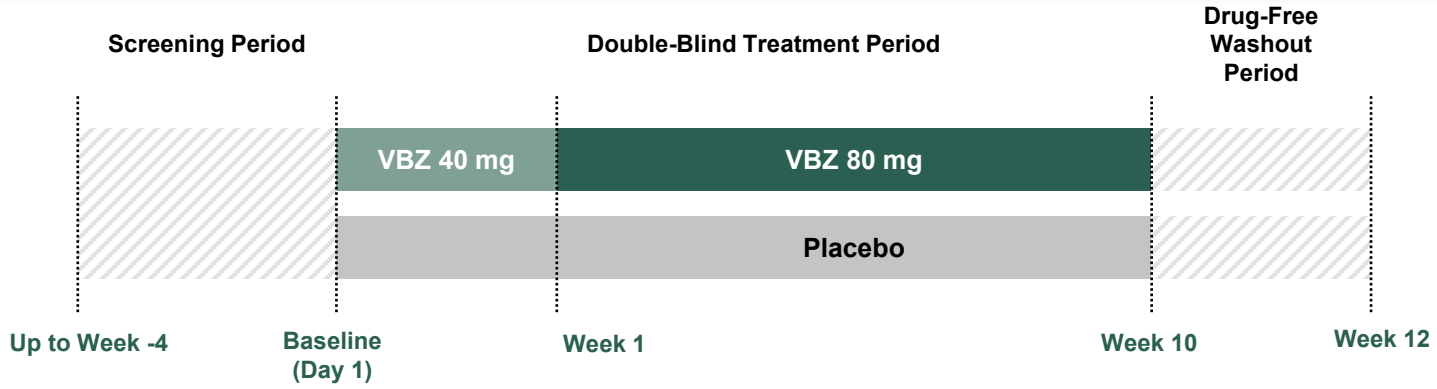
FDA, United States Food and Drug Administration

ATS3019 Study Design[1]

Phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of valbenazine as adjunctive treatment in participants with schizophrenia

Valbenazine has not been approved by the FDA as adjunctive treatment in patients with schizophrenia

Study Design



Expected Study Duration: approximately 16 weeks:
Screening period up to 4 weeks → DBPC treatment period of 10 weeks → drug-free washout period of 2 weeks

- **Approximately 400 participants will be randomized 1:1**
- **Conducted in the US and globally[2]**

DBPC, double-blind placebo-controlled; FDA, United States Food and Drug Administration; VBZ, valbenazine

1. Clinicaltrials.gov. Accessed May 11, 2022. Available at https://clinicaltrials.gov/ct2/show/NCT05110157 | 2. Data on File (VBZ-ATS-0001). Neurocrine Biosciences, Inc.

ATS3019 Key Inclusion Criteria[1]

- ≥ 13 years old
- Medically confirmed diagnosis of schizophrenia as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5)
- Initial diagnosis of schizophrenia must be ≥1 year prior to screening
- Treated with a stable regimen antipsychotic medication
- Outpatient with stable symptomatology

- **Must meet all of the following criteria at screening and Day 1:**
  - Positive and Negative Syndrome Scale (PANSS) total score ≥70
  - PANSS score of ≥4 on at least 1 of the following:
    - P1 (delusions)
    - P3 (hallucinations)
    - P6 (suspiciousness)
    - G9 (unusual thought content)
  - Clinical Global Impression of Severity (CGI-S) score ≥ 4
  - Stable background antipsychotic medication dose between screening and Day 1
  - Stable PANSS total score between screening and Day 1

1. Clinicaltrials.gov. Accessed May 11, 2022. Available at https://clinicaltrials.gov/ct2/show/NCT05110157

ATS3019 Key Exclusion Criteria[1]

- History of treatment resistant schizophrenia (TRS)
- Evidence of depression as measured by a Calgary Depression Scale for Schizophrenia (CDSS) score >8 at screening and Day 1
- Any suicidal behavior or suicidal ideation within 6 months before screening or on Day 1
- Diagnosis of moderate or severe substance use disorder within the 6 months prior to screening
- Prior (within 6 months of Screening) or concomitant use of any VMAT2 inhibitors

VMAT2, vesicular monoamine transporter 2.

1. Clinicaltrials.gov. Accessed May 11, 2022. Available at https://clinicaltrials.gov/ct2/show/NCT05110157

ATS3019 Assessments

Primary Outcome

Change in PANSS total score from baseline to Week 10

Secondary Outcomes

Change in CGI-S score from baseline to Week 10

Change in Personal and Social Performance Scale (PSP) score from baseline to Week 10

CGI-S, Clinical Global Impression of Severity; PANSS, Positive and Negative Symptom Scale.

1. Clinicaltrials.gov. Accessed May 11, 2022. Available at https://clinicaltrials.gov/ct2/show/NCT05110157