Study to Assess the Adverse Events of Oral ABBV-932 in Adult Participants With Depressive Episodes Associated With Bipolar I or II Disorder

NCT07220460

Status	RECRUITING
Phase	Phase 2
Sponsor	AbbVie
Enrollment	200 participants

Key Eligibility Criteria

Inclusion (7)

- Body Mass Index (BMI) e 18.0 to d 40.0 kg/m\^2, inclusive.
- Participants who currently meet the Diagnostic and Statistical Manual of Mental Disorders treatment (DSM-5-TR) criteria for bipolar I or II disorder without psychotic features based on the Mini International Neuropsychiatric Interview (MINI 7.0.2), currently experiencing a depressive episode of at least 4 weeks and not exceeding 12 months.
- Normal physical examination findings, clinical laboratory test results, vital signs, and 12-lead ECG results at screening or abnormal results that are judged not clinically significant by the investigator and documented as such in the eCRF
- Participant with the following psychiatric history:
- No history of psychiatric hospitalization (inpatient or intensive outpatient) in the past 3 months prior to screening.

... and 2 more (see full listing online)

Exclusion (3)

- A total score greater than 12 on the Young Mania Rating Scale (YMRS) at baseline.
- History of an allergic reaction or significant sensitivity to constituents of the study drug (and its excipients) and/or other products in the same class.
- A concurrent medical condition that might interfere with the conduct of the study, confound the interpretation of the study results, or endanger the subject's well-being. This includes any unstable condition, history or evidence of malignancy (other than treated basal or squamous cell carcinoma), or any significant hematologic, endocrine, cardiovascular, respiratory, renal impairment or disease (subjects with eGFR \< 30 mL/min), hepatic (including history of severe hepatic impairment), gastrointestinal, or neurological disorder (if there is a history of such disease but the condition has been stable for more than 1 year, does not require treatment with prohibited medications, and is judged by the investigator not to interfere with participation in the study, the subject may be included in the study).

Locations (48 total)

Ima Clinical Research Phoenix (Alea) /ID# 278047, Phoenix, Arizona, United States
Advanced Research Center /ID# 273474, Anaheim, California, United States
Axiom Research /ID# 273482, Colton, California, United States
... and 45 more locations

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