

An Assessment of Efficacy, Safety, and Pharmacokinetics of NBI-1117568 in Adults With Bipolar I Disorder With Current Mania

NCT07288320

Status	RECRUITING
Phase	Phase 2
Sponsor	Neurocrine Biosciences
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (3)

- Participant has a primary diagnosis of bipolar I disorder.
- The participant has had at least 1 prior documented manic episode that required treatment.
- The participant is experiencing an acute manic episode or manic episode with mixed features, with or without psychotic symptoms.

Exclusion (4)

- Any unstable or poorly controlled medical condition or chronic disease (including history of neurological, hepatic, renal, cardiovascular, gastrointestinal, pulmonary, autoimmune, or endocrine disease that may affect study participation or results), or malignancy within 90 days before the start of screening.
- Primary diagnosis is not bipolar I disorder.
- History of clozapine treatment for treatment-resistant psychosis.
- History of psychiatric hospitalization(s) for e30 consecutive days during the 90 days before the start of screening.

Locations (6 total)

Neurocrine Clinical Site, Garden Grove, California, United States
Neurocrine Clinical Site, Hollywood, California, United States
Neurocrine Clinical Site, San Diego, California, United States
... and 3 more locations