

Study Evaluating the Efficacy and Safety of RAP-219 in Adult Participants With Bipolar I Disorder

NCT07046494

Status	RECRUITING
Phase	Phase 2
Sponsor	Rapport Therapeutics Inc.
Enrollment	224 participants

Key Eligibility Criteria

Inclusion (2)

- Meets the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnosis of bipolar I disorder, with or without psychotic symptoms, as confirmed by the Structured Clinical Interview for DSM-5, Clinical Trials Version (SCID-5-CT). Episode may contain mixed features, as confirmed by Montgomery-Åsberg Depression Rating Scale (MADRS).
- Had at least one prior documented manic episode (with or without psychotic symptoms) that required treatment, within 5 years prior to Visit 1

Exclusion (2)

- History of any of the following diagnoses: a. schizophrenia; schizoaffective disorder; major depressive disorder; moderate or severe substance or alcohol use disorder; as assessed by the SCID-5-CT b. delirium, dementia, amnestic, or other cognitive disorders; borderline, paranoid, histrionic, schizotypal, schizoid, or antisocial personality disorders; by medical history and/or Investigator opinion Note: Any other current diagnoses must be discussed with the Medical Monitor.
- Rapid cyler, defined as experiencing e4 distinct mood episodes (ie, manic or depressive) each meeting full DSM-5 criteria in the previous 12 months, and each separated by e2 months of full or partial remission, or a switch to an episode of the opposite polarity, as assessed by the SCID-5-CT

Locations (22 total)

Pillar Clinical Research - Little Rock, Little Rock, Arkansas, United States
Woodland International Research Group, Little Rock, Arkansas, United States
Woodland Research Northwest, Rogers, Arkansas, United States
... and 19 more locations