

# A Study to Evaluate the Efficacy and Safety of KarXT for the Treatment of Manic Episodes in Bipolar-I Disorder (BALSAM-2)

NCT06951711

---

Status	RECRUITING
Phase	Phase 3
Sponsor	Bristol-Myers Squibb
Enrollment	274 participants

## Key Eligibility Criteria

---

### Inclusion (6)

- Participants must have a primary diagnosis of Bipolar-I disorder established by a comprehensive psychiatric evaluation.
- Participants must be experiencing an acute episode or relapse of mania or mania with mixed features (d 3 weeks).
- Participants must require hospitalization for the acute exacerbation or relapse of mania.
- Participants must have all psychotropic medications washed out in no more than 14 days prior to the first dose of the study drug.
- Participants must have a Young Mania Rating Scale (YMRS) score of e 20 at Screening and at Baseline.

... and 1 more (see full listing online)

### Exclusion (5)

- Participants must not have any primary Diagnostic and Statistical Manual of Mental Disorders (5th Edition, Text Revision) (DSM-5-TR) disorder, other than BP-I with mania or mania with mixed features within 12 months before screening, including BP-I with depression (for previous 3 months only), BP-II disorder, borderline personality disorder, major depressive disorder, and primary psychotic disorder, with the exception of mild anxiety disorders.
- Participants must not have a primary diagnosis of BP-I with rapid cycling (e 4 distinct mood episodes in one year).
- Participants must not have a DSM-5-TR diagnosis of moderate to severe substance use disorder (except tobacco use disorder) within the 12 months before screening, or current use as determined by urine toxicology screen or alcohol test.
- Participants must not be at risk for suicidal behavior at screening or the baseline visit as determined by the Investigator's clinical assessment and the Columbia-Suicide Severity Rating Scale (C-SSRS).
- Participants must not have cirrhosis, liver cancer, clinically significant liver disease based on the liver function test results.

## Locations (69 total)

---

Pillar Clinical Research- Little Rock, Little Rock, Arkansas, United States

Woodland Research Northwest, Rogers, Arkansas, United States

Proscience Research Group, Culver City, California, United States

... and 66 more locations

---

<https://clinicaltrials.gov/study/NCT06951711>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).