A Study to Assess the Long-term Safety of KarXT for the Treatment of Manic Episodes in Bipolar-I Disorder (BALSAM-3)

NCT06929273

Status	RECRUITING
Phase	Phase 3
Sponsor	Bristol-Myers Squibb
Enrollment	450 participants

Key Eligibility Criteria

Inclusion (7)

- Participants who participated in double-blind placebo-controlled study (CN0120036, CN0120037, or CN0120046):
- a. Participants must have completed treatment period of parent study.
- De novo participants who did not participate in double-blind placebo-controlled studies:
- Participants must have primary diagnosis of Bipolar-I disorder established by a comprehensive psychiatric evaluation based on DSM-5-TR criteria and confirmed by the Mini International Neuropsychiatric Interview (MINI, v7.0.2), with symptoms of mania or mixed mania.
- Participants must have Young Mania Rating Scale (YMRS) score of e 14 at Screening and at baseline.

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

Exclusion (9)

- Participants who participated in double-blind placebo-controlled study (CN0120036, CN0120037, or CN0120046):
- a. Discontinuation from any KarXT parent studies.
- De novo participants who did not participate in double-blind placebo-controlled studies:
- All participants with a risk for suicidal behavior at baseline as determined by Investigator's clinical assessment or history of suicidal behavior as assessed on C-SSRS.
- Participants must not have primary diagnosis of BP-I with rapid cycling (ie, e 4 distinct mood episodes in one year).

... and 4 more (see full listing online)

Locations (170 total)

Local Institution - 0120, Glendale, Arizona, United States
Pillar Clinical Research - Richardson, Bentonville, Arkansas, United States
Pillar Clinical Research- Little Rock, Little Rock, Arkansas, United States
... and 167 more locations