A Study to Evaluate the Efficacy and Safety of Adjunctive KarXT for the Treatment of Mania, With or Without Mixed Features, in Participants With Bipolar-I Disorder Taking Lithium, Valproate, or Lamotrigine

NCT07140913

Status	RECRUITING
Phase	Phase 3
Sponsor	Bristol-Myers Squibb
Enrollment	424 participants

Key Eligibility Criteria

Inclusion (6)

- Individuals have a primary diagnosis of Bipolar-I disorder established by a comprehensive psychiatric evaluation based on the DSM-5-TR criteria and confirmed by the Mini International Neuropsychiatric Interview (MINI) version 7.0.2.
- Individual is experiencing an acute exacerbation or relapse of manic episode, with or without mixed features (d 3 weeks).
- The individual requires hospitalization for the acute exacerbation or relapse of mania.
- Body mass index e 18 and d 40 kg/m2.
- Currently experiencing an acute episode of mania or mania with mixed features with a therapeutic dose of lithium, valproate, or lamotrigine. The dose of the mood stabilizer must have remained stable for at least two weeks prior to screening. Additionally, participants on valproate must have been receiving treatment with valproate for a minimum of seven months.

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

Exclusion (8)

- Any primary DSM-5-TR disorder other than BP-I within 12 months before screening (confirmed using MINI version 7.0.2 at screening) including BP-I depression (for previous 3 months only), BP-I with rapid cycling, first manic episode, BP-II, primary psychotic disorder, borderline personality disorder, and major depressive disorder, with the exception of mild anxiety disorders.
- Individual has a DSM-5-TR diagnosis of moderate to severe substance use disorder (except tobacco use disorder) within the 12 months before screening (confirmed using MINI version 7.0.2 at screening), or current use as determined by urine toxicology screen or alcohol test.
- Risk for suicidal behavior at screening as determined by the investigator's clinical assessment and the C-SSRS with an answer "Yes" to item 4 or 5 within 6 months before screening or between screening and baseline, or "Yes" to any of the 5 items (C-SSRS behavior) with an event occurring within the 12 months before screening, or between screening and baseline.
- History of irritable bowel syndrome (with or without constipation) or any serious constipation requiring treatment within the last 6 months.
- History or high risk of urinary retention, gastric retention, or narrow-angle glaucoma.

... and 3 more (see full listing online)

Locations (103 total)

Pillar Clinical Research - Bentonville, Bentonville, Arkansas, United States
Pillar Clinical Research- Little Rock, Little Rock, Arkansas, United States
Clinical Innovations, Inc. dba CITrials, Bellflower, California, United States
... and 100 more locations