Safety and Patient Acceptability of BXCL501 for Treating Acute Agitation in Patients With Bipolar Disorder

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Abstract

Introduction Agitation occurs commonly in persons with acute exacerbations of bipolar disorder and may escalate into aggressive behavior. BXCL501 is an orally dissolving film formulation of dexmedetomidine, a selective alpha2A adrenergic receptor agonist. The tolerability of BXCL501 was evaluated in a Phase 3, randomized, placebo-controlled study for treating acute agitation in patients with bipolar I or II disorder.

Method Patients were randomized 1:1:1 to a single dose of BXCL501 120 µg, BXCL501 180 µg or placebo. Safety and tolerability were assessed from adverse events (AEs), clinical laboratory tests, electrocardiogram (ECG), and vital signs. Patient acceptability was assessed from local buccal irritation, patient-reported acceptability, and taste disturbances.

Results All patients were able to self-administer BXCL501. Among 378 patients randomized and treated, the incidence of AEs with BXCL501 120 µg and 180 µg was 34.9% and 35.7%, respectively, and 17.5% with placebo. The most common AEs with BXCL501 were somnolence, dry mouth, hypotension, and dizziness. Of 53 patients reporting somnolence with BXCL501, 64% were mild and 36% were moderate. No treatment-related cardiac AEs were reported. No patients experienced an AE related to ECG parameters or had a clinically significant abnormal ECG at screening through 24 hours after dosing. Buccal irritation occurred in 3 patients with BXCL501. Patient acceptability was comparable between BXCL501 and placebo, and over 90% of patients reported no unpleasant aftertaste or smell.

Conclusion In this study, BXCL501 was safe and well tolerated. BXCL501 represents a novel, non-invasive treatment for acute agitation associated with bipolar disorder.

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Financial Relationships Details

Commercial Interest	Type of Financial Relationship	Individuals Involved (Self or Spouse)
BioXcel Therapeutics	Employee	Self

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Statement 5 I Agree.

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