Two Randomized, Double-Blind, Placebo-Controlled Trials of Adjunctive Troriluzole, a Novel Glutamate-Modulating Agent, in Obsessive-Compulsive Disorder

Mary Sarah Olson; Loren Aguiar, MD; Alissa Rybicki; Deborah Smith; Tim McCormack; Lia Donahue; Vladimir Conic, MD; Azim Munivar, MD
Biohaven Pharmaceuticals, New Haven, CT, USA

BACKGROUND

- Dysregulation of glutamate, specifically within the cortico-striatal-thalamic pathway, has been implicated in obsessive-compulsive disorder (OCD).
- Troriluzole, a novel glutamate-modulating agent, may normalize synaptic glutamate levels and thus improve OCD symptoms.
- A phase 2 proof-of-concept study in adult patients with OCD revealed a consistent numerical treatment benefit at each time point of troriluzole 200 mg treatment compared with placebo when added to standard-care SSRIs/SNRIs medications.
- The magnitude of change in Yale-Brown Obsessive Compulsive Scale (Y-BOCS) scores indicated a clinically meaningful benefit.

METHODS

- Two identical studies are being conducted, 1 with patients from the USA and 1 with patients from the USA, Canada, the United Kingdom, Spain, Italy, and the Netherlands.
- Each study is a 10-week, randomized, double-blind, placebo-controlled, parallel group design testing troriluzole 280 mg in 700 individuals.
- Patients must have a diagnosis of OCD for ≥ 1 year with inadequate response to an ongoing standard-care medication, as defined by a Y-BOCS score ≥ 22 at screening and baseline.
- The primary endpoint is the change from baseline in the Y-BOCS score.
- The studies began enrollment in December 2020 and are ongoing.

RESULTS

- Analysis of demographic data on patients randomized as of May 25, 2023 (N = 428) revealed that most patients (86%) are women.
- Patients 18 to 30 years of age comprise 53% of those randomized.
- The majority of patients’ self-reported OCD symptoms were men, enrolled in the USA, and White.
- The majority of self-reported Y-BOCS scores at baseline were in the severe range (24-27), with the highest scores in patients 40–49 years of age.
- The proportion of patients reporting more severe Y-BOCS scores increased directly with age.
- We found no association between patients’ self-reported Y-BOCS scores at baseline and the number of years of OCD history.

CONCLUSIONS

- The studies (NCT04641143 and NCT04693351) will investigate the efficacy and safety of troriluzole in patients with OCD.
- Demographic data reveal that the majority of randomized patients are women, enrolled in the USA, and White.
- The majority of self-reported Y-BOCS scores at baseline were in the severe range (24-27), with the highest scores in patients 40–49 years of age.
- The proportion of patients reporting more severe Y-BOCS scores increased directly with age.
- We found no association between patients’ self-reported Y-BOCS scores at baseline and the number of years of OCD history.

REFERENCES


This research was supported by Biohaven.

To download a copy of this poster, scan QR code.