

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

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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 40-59 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 score at baseline and the number of years of OCD history

Disclosures: MSO, LM, AR, DS, TM, LD, VC, and AM are employed by and hold stock/stock options in Biohaven.

References

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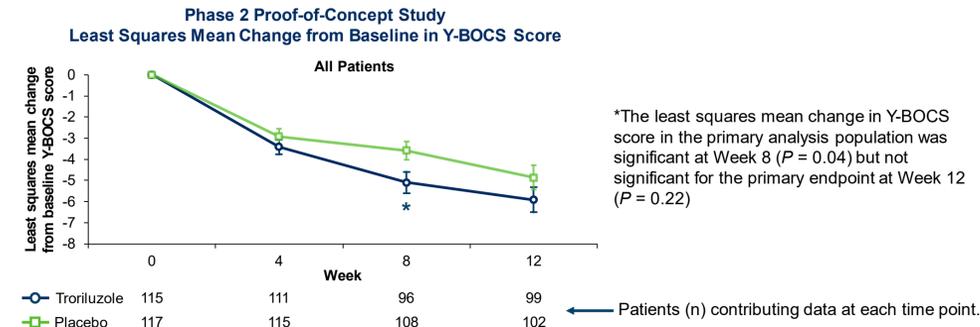
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BACKGROUND

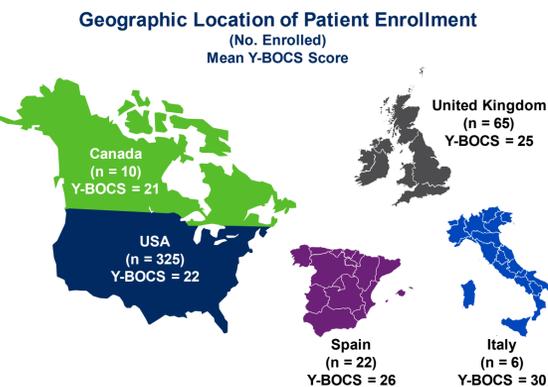
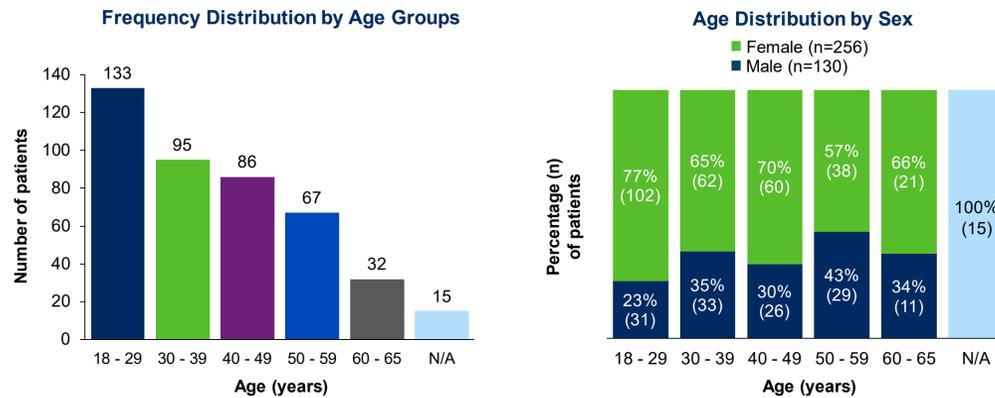
- Dysregulation of glutamate, specifically within the cortico-striatal-thalamic pathway, has been implicated in obsessive-compulsive disorder (OCD)
- Troriluzole, a novel glutamate-modulating agent, may normalize synaptic glutamate levels and thus improve OCD symptoms
- A phase 2 proof-of-concept study 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 SSRI/SNRI medications
- The magnitude of change in Yale-Brown Obsessive Compulsive Scale (Y-BOCS) scores indicated a clinically meaningful benefit



RESULTS

- Analysis of demographic data on patients randomized as of May 25, 2023 (N = 428) revealed that most patients (66%) are women
- Patients 18 to 39 years of age comprise 53% of those randomized
- The ranges of patients' baseline Y-BOCS scores are 22-23 (11%), 24-27 (41%), 28-31 (33%), and 32-40 (15%)
- The majority of patients (54%) reported less than 10 years of OCD history, while 21% reported 11 to 20 years of OCD history, and 21% reported ≥ 21 years of OCD history
- A greater proportion of females than males reported 6 to 10 years and 11 to 20 years of OCD history

PATIENT DEMOGRAPHICS



Race Distribution Among Patients

Race	n (%)
American Indian or Alaska Native	1 (0.2)
Asian	19 (4.4)
Black or African American	17 (4.0)
Native Hawaiian /Other Pacific Islander	1 (0.2)
Not reported	3 (0.7)
N/A	15 (3.5)
Other	13 (3.0)
White	359 (83.9)

OBJECTIVE

- Describe the design, scientific rationale, and demographic characteristics of the studies

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

BASELINE CHARACTERISTICS

