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

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DISCLOSURES:
- DM: employed by and holds stock/stock options in Biohaven, AM: employed by and holds stock/stock options in Biohaven.
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RESULTS:
- Analysis of demographic data on patients randomized as of August 1, 2022 (N = 296) reveals that most patients (68%) are women
- Patients 18-39 years of age comprise 51% of those randomized
- The ranges of patients' baseline Y-BOCS scores were 22-25 (12%), 26-27 (41%), 28-31 (31%), and 32-40 (16%)
- The majority of patients (55%) reported 2-10 years of OCD history, while 20% reported 11-20 years of OCD history and 17% reported ≥ 21 years of OCD history
- A greater proportion of males than females reported 2-5 years or ≥ 21 years of OCD history

CONCLUSIONS:
The studies (NCT04641143 and NCT04933351) 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 participants 40-59 years of age

The proportion of participants reporting more severe Y-BOCS scores increases directly with age

We found no association between participants' self-reported Y-BOCS score at baseline and the number of years of OCD history

In this research, young men were over-represented compared to women (41% vs. 20% of randomized subjects).

Intravenous (IV) medications are given to subjects in the study, and their effect on the clinical outcomes is measured.

The primary endpoint is change in Y-BOCS score from baseline at Week 12 (P = 0.04) but not significant for the primary endpoint at Week 28 (P = 0.12).

The patients in the study are predominantly from the USA, Canada, and the United Kingdom.

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, parallel group design treating 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 change in Y-BOCS score from baseline to Week 10.
- The studies began enrollment in December 2020 and are ongoing.

BASELINE CHARACTERISTICS:

BASLINE-Y-BOCS SCORE BY PATIENT AGE

Scatterplot of Reported Years of OCD History and Baseline Y-BOCS Score

Number of patients

Boys

Girls

Baseline Y-BOCS Scores by Reported Age

Frequency Distribution of Baseline Y-BOCS Scores

Frequency Distribution of Reported Years of OCD History

BASELINE-Y-BOCS SCORE BY GENDER

Number of patients

Frequency Distribution of Baseline Y-BOCS Scores by Gender

Age (years)

Age (years)

Number of patients

Age (years)

Geographic Location of Patient Enrollment (No. Enrolled; Mean Y-BOCS Score)

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