



Community Statement: BRAVE Phase 3 Pediatric Study of Omaveloxolone

Dear FA Community,

We are excited to share our plan to initiate the BRAVE study, a global Phase 3 study evaluating the effects and safety of omaveloxolone in children with Friedreich ataxia (FA) between the ages of 2 – 15 years. We join in the community's sense of urgency to bring potential treatments to people living with FA, and we honor the dedication and efforts of everyone working toward this important mission. As you may know, the use of omaveloxolone within the pediatric population for children younger than 16 years of age is considered investigational in that its safety and effectiveness have not been established, and the use has not been approved by the U.S Food and Drug Administration (FDA).

The design of this global Phase 3 study has been informed by input from previous studies and investigators, health authorities, global medical experts, and the FA community. The global Phase 3 BRAVE study will initially include six sites across the United States, with the first two sites expected to open enrollment this summer and the remainder throughout this year. For the most up-to-date information on trial locations and details, we encourage you to visit clinicaltrials.gov.

Individuals interested in participating in this study should speak with their healthcare provider. They can also email Biogen at clinicaltrials@biogen.com. Individuals located in the U.S. can also call the Biogen Clinical Trials Center at 866-633-4636. Both clinicaltrials.gov (NCT06953583) and Biogen Trial Link ([Biogen Trial Link](#)) will be updated as more information about the BRAVE study becomes available.

We deeply appreciate the community's invaluable contributions to advance scientific research and understanding of FA. We look forward to sharing more updates on the BRAVE study.

Sincerely,
Biogen Team