



June 18, 2025

Subject: Biogen Initiates Phase 3 Pediatric Study of Omaveloxolone for the Treatment of FA

Dear NAF & the FA Community,

We are excited to share that the first site is open for enrollment in the BRAVE study, a global Phase 3 clinical trial with the goal of evaluating the efficacy and safety of omaveloxolone in ~255 children with Friedreich ataxia (FA) between the ages of 2 to 15. Children with FA may qualify for the study regardless of their walking ability (i.e., non-ambulatory and ambulatory individuals).

Initiating the BRAVE study is an important step in our journey to address the unmet needs of children and adolescents living with FA. Enrollment is now underway in the United States (U.S.), and the first patient has been dosed. Additional U.S. sites will open this summer, and we plan to open BRAVE study sites around the world pending final alignment with local regulators and ethics committees.

In Part 1 of the study, participants will be randomly assigned to receive either omaveloxolone or placebo for 52 weeks. For every three patients that join the study, two will receive omaveloxolone, and one will receive placebo. The primary objective of the study is to evaluate changes in upright stability – a measure including how well someone can stay balanced while standing and walking – after one year of treatment. Upright stability is identified as a sensitive way to measure disease progression in children living with FA. In Part 2, all participants will receive omaveloxolone for up to 104 weeks to understand how the drug works over the long-term.

The design of this global Phase 3 study has been informed by previous studies and input from investigators, global medical experts, and the FA community. The study is set to operate in 6 sites across the U.S. and additional sites in other countries.

Individuals interested in participating in this study should speak with their healthcare providers. They can also email Biogen at clinicaltrials@biogen.com, and individuals located in the U.S. have the additional option to call the Biogen Clinical Trials Center at 866-633-4636, where they will have the opportunity to be connected with a BRAVE study Patient Navigator. Both clinicaltrials.gov ([NCT06953583](https://clinicaltrials.gov/ct2/show/study/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 contributions to scientific research and are committed to supporting individuals with FA and their families through their journey.

Sincerely,
Biogen Team