



To: Jennifer Farmer (CEO, FARA)

CC: Debbie Drell, Patient Advocacy Lead, FA & Rare Disease

From: Stephanie Fradette, Head of Clinical Development, Neuromuscular

Update on Omaveloxolone Program

Dear Friedreich Ataxia (FA) Community,

We are pleased to provide an update on the omaveloxolone program, reflecting our shared commitment to advancing care and research for individuals living with FA.

BRAVE Phase 3 Study in Pediatrics – Enrollment Milestone reached and additional US sites open

We are excited to announce that the BRAVE study has reached 50% enrollment, with 128 participants enrolled. As a reminder, the study aims to enroll up to 255 participants. In addition to the great progress on enrollment, six of seven U.S. sites are now active and enrolling participants in the BRAVE study, Biogen's global Phase 3 clinical trial evaluating the efficacy and safety of omaveloxolone in children aged 2 to 15 years with FA. The BRAVE study is actively enrolling in sites in the U.S. in the following locations:

1. UF Health – Gainesville, Florida
2. USF Health – Tampa, Florida
3. Children's Hospital of Pennsylvania – Philadelphia, Pennsylvania
4. St. Jude Children's Research Hospital – Memphis, Tennessee
5. Children's Hospital of the King's Daughters – Norfolk, Virginia
6. Seattle Children's Hospital – Seattle, Washington

We expect one additional U.S. site on the west coast (UCLA Neurology at Westwood) to begin enrolling in the coming months. Additional sites are open in other countries. Please check the BRAVE study posting at [Biogen Trial Link](#) for the latest information.

The study is now enrolling children ages 2 to <7 years, in addition to those ages 7 to 15 years. This important step allows us to address the unmet needs of a broader pediatric population across ages and walking ability (ambulatory and non-ambulatory).

About the BRAVE Study

The BRAVE study design has been shaped by insights from previous research, investigators, global medical experts, and the FA community. In Part 1, up to 255 participants are randomly assigned to receive either omaveloxolone or placebo for 52 weeks with twice as many participants receiving omaveloxolone as those receiving placebo. The primary objective of the study is to evaluate changes in upright stability - a sensitive measure of disease progression in the pediatric population after 1 year of treatment. In Part 2, all participants will receive omaveloxolone for up to 104 weeks to assess long-term effects.

Individuals interested in participating should consult their healthcare providers. For more information, please contact Biogen at clinicaltrials@biogen.com. To connect with a BRAVE study Patient Navigator,



call 877-223-3576, access code 57078 (US), or email biogenBRAVE_patientnavigator@thermofisher.com. Updates will be posted on clinicaltrials.gov (NCT06953583) and [Biogen Trial Link](#) as the study progresses.

Completion of the MOXIe Open Label Extension (OLE) Study

We are pleased to share that the final participant has successfully completed the MOXIe open label extension (OLE) study. The MOXIe study was an international, double-blind, randomized, placebo-controlled, multicenter, trial followed by an OLE. The study was designed to learn more about the safety of omaveloxolone and how it affects physical effort, movement, coordination, and how participants with FA feel in daily life. The MOXIe study was central to the regulatory approvals of omaveloxolone for the treatment of FA in patients 16 years and older. The OLE part of MOXIe observed the safety and efficacy of omaveloxolone when used for up to three years.

Completion of the study is a major milestone made possible by the dedication and partnership of participants, their families, the investigators and site staff, and the broader FA community. Your time, commitment, and contributions have been invaluable in advancing scientific understanding and therapeutic options for FA.

Biogen Exploring Tablet for Oral Suspension for Alternative Administration of Omaveloxolone

We are pleased to share that we have recently initiated a Phase 1 study to assess the bioequivalence of a tablet form of omaveloxolone that is suspended in liquid relative to the oral capsule. Currently, omaveloxolone is taken by mouth as capsules or capsule contents sprinkled over applesauce. The main goal of the study is to learn if omaveloxolone is processed similarly in the body of healthy adults when taken as tablets in an oral suspension compared to the currently available capsules.

Biogen understands that there some people may have trouble swallowing capsules and desires to make more options available to patients to take omaveloxolone. If the study is successful and the new tablet for oral suspension is approved by regulators, this formulation would enable delivery of omaveloxolone in liquid form.

Updates will be posted on clinicaltrials.gov (NCT07297199).

We deeply appreciate the FA community's ongoing partnership and contributions to scientific research. Biogen remains committed to supporting individuals with FA and their families throughout their journey.

Sincerely,

The Biogen Team