An Informational Webinar with Biogen Recorded May 22, 2025

Question & Answer Summary as provided by Biogen

Below is a summary of the question and answer session with Steph Fradette, PharmD, Vice President and Head of Neuromuscular Development Unit at Biogen:

Study Countries & Site Logistics:

- Which countries and sites are running BRAVE?
    - BRAVE is currently planned at approximately 30 sites across 16 countries. The full listing of sites is available at clinicaltrials.gov.
- Will Biogen add more sites to the study?
    - Biogen does not plan to add additional sites to the study at this time.
- If I live in a country where there aren't any study sites, can I travel cross-border to participate?
    - Cross-border referrals are evaluated on a case-by-case basis. To inquire about eligibility, please contact the Patient Navigator support line at 1-877-223-3576 (access code 57078)
- What is Biogen's travel policy?
    - Travel support for clinical trial participants may be available in the form of coordination and coverage of expenses related to the study. Depending on a participant's distance to the study location, this may include ground transportation, flight, and hotel.

Enrollment & Participation Requirements:

- How can I (or my child) participate in BRAVE?
    - If you or your child are interested in participating in the BRAVE study, please contact us at clinicaltrials@biogen.com or contact the patient navigator support line at 1-877-223-3576 (access code 57078). These resources are there to help you and your child navigate a path towards participation in the study.
    - It is important to note that not all study sites will be ready to accept patients right away. Biogen is working closely with all of their sites globally to ensure they can start participating in the study as soon as possible.

    - Currently, there is no plan for a lottery, however this may change based on the volume and timing of interested patients.

- Can you share more about eligibility criteria?
    - While the primary analysis population is ambulatory participants between 7 and < 16 years of age, the trial will also include up to 36 non-ambulatory participants and up to 12 participants who are 2 to < 7 years old.
    - Participants with mild to moderate cardiomyopathy are eligible to participate in the trial. In order to be eligible for the trial, participants must have a brain natriuretic peptide (BNP) level of 200 pg/mL or less at screening, as well as an ejection fraction of 40% or more. If you are unsure whether your child meets these criteria, your study doctor can help you find out.
- If my child will turn 16 during the study, can they still participate and continue in the trial?
    - Yes. Eligibility is determined by your child's age at the start of the trial. They must be between 2 and < 16 years of age at the start of the trial to participate. They will complete all planned visits and assessments even if they turn 16 during the study.
- Will there be a limit to how many people can enroll in each country where sites are active?
    - There is no limit to how many people can enroll in each country. This will be competitive enrollment until the total number of patients required for the study is reached (255 patients).
- Can I take other medications while participating?
    - You may continue taking most of your routine medications while participating in this trial, but there are some medications that will not be allowed. The study team will explain which medications you can't take during the study. Importantly, Biogen requires study participants to refrain from taking any other drug being investigated for or approved for the treatment of FA.
- If a new therapy is approved to treat FA, will participants be allowed to use it?
    - Biogen require study participants to refrain from taking any other drug being investigated for or approved for the treatment of FA during their participation in the trial. This will allow us to clearly understand how omaveloxolone

works, both in terms of how it is helping and what side effects it may cause. Biogen will continue to assess this requirement.

- If my child or I have not received genetic confirmation of FA, will you offer genetic testing in the study?
    - Patients must have genetic confirmation of FA to enter the study.

End of Study:

- What happens if the study fails but I believe the drug is working for my child or me?
    - In the event this study fails to demonstrate the safety and efficacy of omaveloxolone in children with FA, all study participants will work with their doctors to determine the best options available once the study has completed.
- What happens when the study is over?
    - At the completion of the study if it demonstrates positive risk benefit and Biogen decides to proceed with filing for market authorizations, study participants may have access through commercial channels or potentially other access mechanisms.
- When do you expect approval for pediatric patients ?
    - Biogen is not able to comment on the timing of potential regulatory engagements at this time. Biogen's immediate priority is successful execution of the BRAVE study, and Biogen is hopeful that the data will support an expanded label to include pediatric patients. As a reminder, the study is expected to start this summer, and the estimated primary completion date is November 2027.