

FARA is excited to share news that Part 2 of the Phase II MOXIe study (RTA 408 or omaveloxolone), sponsored by Reata, is open, and needs 100 individuals with FA to participate. This is a randomized, placebo-controlled, double-blind, parallel-group study to evaluate the safety and efficacy of omaveloxolone (RTA 408) 150 mg in patients with Friedreich's ataxia. Participants will be randomized 1:1 to either receive omaveloxolone (RTA 408) 150 mg or placebo.

This is an international study with sites in the United States, Europe, and Australia.

You will also see the key inclusion and exclusion criteria which include:

Inclusion Criteria include:

1. Have genetically confirmed Friedreich's ataxia
2. Be male or female and ≥ 16 years of age and ≤ 40 years of age
3. Have no changes to exercise regimen within 30 days prior to Study Day 1 and be willing to remain on the same exercise regimen during the 16-week study period
4. Have the ability to complete maximal exercise testing - this test is performed on a recumbent exercise bike, you need to be able to pedal the bike at a regular rate for 10-15 minutes
5. Have a modified FARS score ≥ 20 and ≤ 80 - this is determined at your screening visit

Exclusion Criteria include:

1. Prior participation in a trial with omaveloxolone (RTA 408)
2. Uncontrolled diabetes
3. History of clinically significant heart disease
4. Participation in any other interventional clinical study within 30 days prior to Study Day 1

Clinicaltrials.gov lists all of the sites currently participating and the full list of inclusion and exclusion criteria - <https://www.clinicaltrials.gov/ct2/show/NCT02255435>

If you are interested in the study or have questions about the study, we encourage you identify the site that is geographically closest to you and contact the study coordinator. Some of the sites can begin screening and enrollment now, however not all the sites are fully approved and operational yet. If your site is not open yet you can still contact the site and discuss your questions with the coordinators and get your name on a list with the site so they contact you directly as soon as they can start screening.

Get updates on the MOXIe Phase 2 Study

Please join Jennifer Farmer, Executive Director, FARA & Dr. Colin Meyer, CMO of [Reata Pharmaceuticals](#), for one of two upcoming meetings to discuss the [MOXIe](#) clinical trial in more detail.

Reata will be hosting the online Webex meetings in September to discuss recent MOXIe Phase 2 data plus study updates and next steps for the ongoing Phase 2- Part 2 portion of MOXIe. Reata is evaluating the safety and effectiveness of an investigational medication, RTA 408 (omaveloxolone), in Friedreich's ataxia.

Meeting Dates and Times

There will be two meetings in the next few weeks. The same information will be presented at both meetings, so pick the time that best fits your schedule:

- Wednesday, September 6 at 2:30pm PDT/5:30pm EDT
- Thursday, September 7 at 8:00am PST/11:00am EDT

Purpose

The purpose of these meetings is to provide an update the study and introduce the Part 2 portion of the study to the patient community, including study participation, eligibility criteria, how to enroll, study status, etc. The Webex meetings will include time at the end for FARA/ Reata to answer questions from the participants.

Target Audience

This event is aimed at any interested individuals affected by Friedreich's ataxia and/or family members.

What is a Webex Meeting?

A Webex is an online meeting that includes audio and screen sharing. All you need is an internet connection!

How to Participate

To register for one of the online Webex meetings, please contact Hanh Nguyen at Hanh.Nguyen@reatapharma.com. Then simply follow the link provided at the appropriate time. In order to receive the link to join the Webex meeting, **you must register in advance**.

Other sources of information

Additional information about RTA 408 (omaveloxolone), the medication being used in the study, is available from a recorded presentation to the FA community, June 2nd, 2017 via this video link where Dr. David Lynch presented the results at FARA's Research Update following the Patient Focused Drug Development meeting:

go to <https://www.youtube.com/watch?v=Va1D4SqrSfw&feature=youtu.be>

skip forward to the 6 hour 42min time to go directly to Dr. Lynch's presentation.

Click here to see the Reata press release that summarizes the results

- <http://investors.reatapharma.com/phoenix.zhtml?c=254306&p=irol-newsArticle&ID=2278245>