Alexion’s Myasthenia Gravis Clinical Trial

Alexion Pharmaceuticals is conducting a clinical trial to determine if eculizumab is effective for the treatment of patient with refractory generalized Myasthenia Gravis (gMG). This is a global trial, with approximately 100 sites in North and South America, Europe and Asian-Pacific countries are taking part. This study is currently looking for patients with refractory gMG.

To participate in this trial you must have significant impairment of your activities of daily living, like combing your hair or getting up out of a chair as a result of your Myasthenia Gravis, you must be at least 18 years old, and have a positive test for the AChR antibody. If you do not know if you are positive for this antibody test your doctor will be able to tell you. In addition you must have been treated with at least 2 different medications or require IVIg or Plasmapheresis to treat your MG.

This clinical trial is an “add on study”, which means you are permitted to continue your present MG medications and receive the study medication. In this study, half of the participants will receive eculizumab and the other half will receive placebo, which means you have a 50% chance of receiving eculizumab and a 50% chance of receiving placebo. Placebo looks like the active drug. This is a “double blind study” which means that neither you nor the study doctor or his/her staff know whether you are receiving eculizumab or placebo. In fact, no one who is involved in the study will know what you received until the study is complete. The medication is given intravenously, initially weekly for 5 weeks and then every 2 weeks. You will have to come to the doctor’s office or infusion center for the infusion. You will remain in the study for 26 weeks. Once you complete your 26 weeks you may be eligible to enroll in a second study where all patients will receive eculizumab. More information on this study can be found at www.clinicaltrials.gov. NTC01997229. This study is now enrolling, if you are interested in participating in this study, you may contact the site near you directly or Alexion medical team at wangj@alxn.com.

As with all medications there are potential side effects. Your doctor will discuss these with you and they will be detailed in the informed consent you will need to sign to be part of the study.

About Eculizumab
Eculizumab is not approved for treatment of Myasthenia Gravis. Eculizumab is a monoclonal antibody that blocks one component of the complement pathway, part of the immune system. Activation of the complement pathway is believed in part responsible for the muscle weakness you are experiencing. A pilot study of eculizumab in 14 patients with refractory MG suggested that treatment with eculizumab improved MG symptoms. This study is intended to confirm that finding.