Transcript Details
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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Investigating Inebilizumab for Generalized Myasthenia Gravis: Results from MINT

Announcer:
Welcome to *NeuroFrontiers* on ReachMD. On this episode, we'll hear from Dr. Richard Nowak, who's an Associate Professor of Neurology at Yale University and the founding Director of both the Program for Clinical and Translational Neuromuscular Research and the Yale Myasthenia Gravis Clinic. He's also the global principal investigator for the Myasthenia Gravis Inebilizumab Trial, or MINT for short, which is what he'll be talking about today. Here's Dr. Nowak now.

Dr. Nowak:
MINT stands for Myasthenia Gravis Inebilizumab Trial, and it was a phase 3 clinical trial with the main objective to evaluate the safety and efficacy of inebilizumab in patients with generalized myasthenia gravis with either acetylcholine receptor or muscle-specific kinase disease.

The clinical design of the trial: it was a prospective, randomized, placebo-controlled clinical trial that randomized patients to either inebilizumab or placebo 1:1. We had a randomized control period lasting 26 weeks in the entire or overall study population, but the randomized control period lasted 52 weeks in the acetylcholine receptor antibody subtype. The study enrolled patients with generalized myasthenia gravis with an MGFA classification ranging from 2 to 4. We included patients that had either acetylcholine receptor antibody-positive or muscle-specific kinase-positive disease. Patients that were enrolled were moderate to severe in terms of their disease intensity as defined by an MG-ADL score minimum of 6 or higher.

The primary endpoint was a change from baseline in MG-ADL score at week 26 for the overall study population. Key secondary outcomes included looking at QMG score change from baseline at the week 26 timepoint. Additional secondary outcomes included looking at the autoantibody subtypes, so looking at the acetylcholine receptor and muscle-specific kinase on their MG-ADL score change from baseline to week 26, as well as the QMG score change. In terms of looking further out at the week 52, we looked specifically at those patients in the AChR antibody subtype, again, looking at the score change in MG-ADL and QMG in comparison to their baseline scores.

The primary endpoint was met, which showed a statistically significant reduction in MG-ADL score both for the ADL—that was the primary—and the key secondary, which was the QMG. But we also looked at the acetylcholine receptor and MuSK antibody subtype. We found that in both the MG-ADL scores, there was a significant reduction in the autoantibody subtype. Then, looking at the 52-week timepoint, which we have data for in the acetylcholine receptor antibody population, the MG-ADL score as well as the QMG score changes were significantly reduced in the treatment group as compared to placebo, so very encouraging study results for both acetylcholine receptor and MuSK and, in general, in the combined study population during the randomized control period.

Our phase 3 clinical trial was recently published in *The New England Journal of Medicine*, so do please check out the study manuscript for additional details and information with regard to the safety and efficacy of inebilizumab in patients with generalized myasthenia gravis.

Announcer:
That was Dr. Richard Nowak discussing his phase 3 trial on using inebilizumab for generalized myasthenia gravis treatment. To access this and other episodes in our series, visit *NeuroFrontiers* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!