Transcript Details

This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/neurofrontiers/updates-from-mint-inebilizumab-reduces-relapses-and-rescue-therapy-use/35869/

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Updates from MINT: Inebilizumab Reduces Relapses and Rescue Therapy Use

Announcer:
You're listening to *NeuroFrontiers* on ReachMD, and on this episode, we'll hear from Dr. Richard Nowak. Not only is he 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, but he's also the global principal investigator for the Myasthenia Gravis Inebilizumab Trial, otherwise known as MINT. Dr. Nowak will be sharing new data from MINT, which focused on how inebilizumab may reduce the risk of disease exacerbations and the need for rescue therapy. Let's hear from him now.

Dr. Nowak:
MINT was a Phase 3 placebo-controlled clinical trial that evaluated inebilizumab in patients with generalized myasthenia gravis that either had acetylcholine receptor or muscle-specific autoantibodies. In our primary study, we demonstrated that there was a significant improvement based on our primary endpoint looking at a difference in the MG-ADL score as well as some of the key secondary outcomes, specifically the QMG score in patients treated with inebilizumab as compared to those that were assigned to placebo. So again, the primary study demonstrated clinical benefit and safety for patients with generalized myasthenia gravis with either of those two autoantibodies.

So as part of our prespecified endpoints, we wanted to understand the impact of inebilizumab on both rescue therapy use as well as MG exacerbations. These are things that occur as part of the natural course of patients with myasthenia gravis. And we looked at the difference between the two groups, specifically looking at exacerbation rate to start, and we demonstrated in the combined study population through week 26, which was the primary endpoint, that patients who were assigned to inebilizumab had a 16 percent relapse rate as compared to 35 percent in those that received placebo, demonstrating a clinically significant difference. Additionally, the randomized control period was 52 weeks in our AChR group, and we see the same or similar trend where the patients who were assigned to inebilizumab had a 20 percent MG exacerbation rate as compared to 45.2 percent in those that were assigned to the placebo group, demonstrating a significant difference.

Furthermore, we looked at rescue therapy use. Rescue therapy was defined by the use of either IVIG or plasmapheresis. These are both typical and standard of care rescue therapy options for patients with exacerbations, and we found through week 26 in the combined study population that those in the inebilizumab group had 8.4 percent of rescue therapy use compared to 23.9 percent in the placebo group. In the AChR group that had their RCP go through week 52, we found a similar trend: 11 percent versus 35 percent in the placebo group, again showing a significant reduction if you compare it to the placebo group.

So our secondary analyses looking at exacerbation and rescue therapy use continues to support the idea that inebilizumab, an anti-CD19-directed B cell therapy, is beneficial for our patients. It just provides additional information, and it tells us about how the burden of disease is reduced for our patients during the randomized control period by looking at these two additional prespecified secondary analysis endpoints.

Additionally, I would like to note that participants enrolled in MINT had the opportunity to enroll in our open-label extension, which we are following patients for up to an approximate 3-year duration, and so additional data and information about the role of inebilizumab is to come based on some additional analysis that we have planned and currently underway in the coming months and most certainly in the coming one to two years from MINT.

Announcer:

That was Dr. Richard Nowak sharing new data from MINT on inebilizumab's impact on exacerbation risk and the need for rescue therapy in generalized myasthenia gravis patients. 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!