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Released: 04/02/2025
Valid until: 04/02/2026
Time needed to complete: 58m

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New Frontiers in MG: How FcRn Antagonists Are Changing MG Therapy

Announcer:
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Dr. Bril:
This is CME on ReachMD, and I'm Dr. Vera Bril. Here with me today is Dr. Nicholas Silvestri.

Let's take a look at the FDA-approved and investigative FcRn antagonists that have shown both efficacy and safety in the management of GMG.

Dr. Silvestri, what do our listeners need to know?

Dr. Silvestri:
Thanks very much, Dr. Bril. I'm going to do this in chronological order, so the first study of an FcRn antagonist in the treatment of generalized myasthenia gravis was efgartigimod. And this was looked at in the ADAPT phase 3 trial. And this was a trial of efgartigimod plus standard of care therapy versus placebo and standard of care therapy in patients with generalized myasthenia gravis. The key outcome measure, the primary outcome measure, was change from baseline and MG-ADL percent of responders. And there were several key secondary outcome measures, including the percentage of QMG responders. And suffice it to say that there was a statistically significant difference between those patients treated with efgartigimod versus placebo in terms of the MG-ADL percent responders, as well as QMG percent responders and a number of other secondary outcome measures. And this ultimately led to the approval of efgartigimod in the treatment of patients with acetylcholine receptor-positive generalized myasthenia gravis.

The next trial was the MycarinG trial. This was the phase 3 trial of rozanolixizumab in patients with gMG. And similar to the ADAPT trial, this trial was also positive insofar as it demonstrated statistically significant and clinically meaningful improvements in MG-ADL, QMG, and many other scores. Of note, rozanolixizumab also demonstrated significance in the treatment not only of acetylcholine receptor-positive disease, but also MuSK-positive disease, and that led to the FDA approval for both forms of treatment of myasthenia gravis.

The next trial was the VIVACITY trial. This was a phase 3 trial of nipocalimab, another FcRn antagonist, administered as biweekly infusions in patients with GMG. This study was most recently read out not that long ago. And it, like the previous two studies, demonstrated improvements that were statistically significant in a number of measures, including MG-ADL and QMG, which has led to the filing for FDA approval for this medication.

And then finally, I'll touch on batoclimab, which is currently in the midst of a phase 3 trial. Batoclimab is another FcRn antagonist. We hope to have a readout on this medication at some point in the next few months.

Dr. Bril:
Thank you, Dr. Silvestri. I think this is a very exciting time for us because we have these new, focused treatments that work very quickly. The side effect profiles are mild to moderate and include headaches, increased risk of infections, such as upper respiratory tract

and urinary tract infection. But these risks do not increase with time or number of repeated cycles.

And the other observation is that with repeated cycles of treatment, the same degree of efficacy is seen with these agents.

So this is an extremely exciting time to be treating patients with generalized MG, in that you have more focused treatment with fewer side effects.

Well, this was a great but brief discussion. Hopefully you can put some of these tips into your own practice tomorrow. And thank you again for listening.

Announcer:
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