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Released: 12/17/2024
Valid until: 12/17/2025
Time needed to complete: 57m

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Clinical Benefits of FcRn Inhibitors: Innovations in CIDP Management and Treatment

Announcer:
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Dr. Allen:
This is CME on ReachMD. I'm Dr. Jeffrey Allen. Joining me today is Dr. Nicholas Silvestri.

Nick, let's consider clinical trials on FcRn inhibitors, such as the ADHERE trial. What key findings from those trials can you share?

Dr. Silvestri:
Yeah. Let's just take a minute to go through the ADHERE study because it was such a novel trial. So ADHERE was a phase 3, multicenter, randomized, blinded, placebo-controlled trial, and it was really done rigorously. So there was a patient selection that was done and there was an adjudication committee that made sure that, based on the records, that patients were felt to have CIDP based on EFNS/PNS criteria.

And then there's a run-in phase where patients that were treated either with IVIG, subq Ig, corticosteroids, were stopped on those medications to make sure they still had active disease. And only patients that worsened during that run-in phase actually moved on to stage A. If they didn't, they skipped the run-in. And so then in stage A, patients were given open-label efgartigimod with hyaluronidase, and the primary endpoint were the percentage of patients with clinical improvement. Only patients with documented improvement in stage A went to stage B. In stage B, in that case, patients were randomized to either continue to receive efgartigimod subq with hyaluronidase or placebo. And in that stage, the primary endpoint was the time to first relapse.

Now, in the open-label stage A portion, again, this is the portion where all patients were treated, of all participants, about two-thirds actually demonstrated improvement. So another way to look at it is 2 out of 3 patients that received the medication had improvement on the medication, one-third did not.

And then, in stage B, the double-blinded efgartigimod and hyaluronidase versus placebo stage, patients treated with efgartigimod had a 61% lower risk of relapse versus placebo. So in both cases, in stage A about a 66.5% response with efgartigimod, and stage B, about a 61% lower risk of relapse versus placebo. And the results of this clinical trial are what led to the approval of efgartigimod and hyaluronidase in the treatment of CIDP in the United States.

Dr. Allen:
Yeah, that's a great summary. It was a big, big trial. Over 600 patients were enrolled in the trial; over 300 patients ended up getting randomized. It was very complex, as you pointed out, with the adjudication panel, and then the run-in phase where you had to withdraw from your standard therapies, and then stage A open-label improvement, and then the randomized withdrawal design phase. It was an event-driven trial, of course, and so once that 88th event occurred, then the trial was closed and the data was analyzed. And because of

that, there were patients in different phases of the trial when it was closed.

It's also exciting to note that there's an open-label extension to that trial that's still ongoing right now. So we look forward to seeing those results.

Dr. Silvestri:
Yeah. And I will also point out, we spent a lot of time talking about trial design and efficacy, but in general, I would just like to point out, too, efgartigimod was generally well-tolerated by patients.

I think the biggest side effect were injection site reactions or skin reactions, which is not at all that uncommon in subcutaneously infused medication. But generally speaking, other side effects such as risk of infection, etc., were fairly low compared with placebo and compared with traditional agents that we use.

Dr. Allen:
Yeah, absolutely true. We're, of course, interested in following that over time and in an open-label setting or in a real-world setting, and also in other disease states as well. But it's good to know that at least from the ADHERE trial, no major red flags came up from a safety standpoint.

Well, I think that's all the time we have. Thanks so much for that discussion. And thanks to our listeners for tuning in.

Announcer:
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