

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/heart-matters/enlicitide-ldl-c-management-coralreef-lipids/54152/>

ReachMD

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

Enlicitide for LDL-C Management: Insights from CORALreef Lipids

Announcer:

You're listening to *Heart Matters* on ReachMD. On this episode, Dr. Ann Marie Navar, an Associate Professor of Cardiology at the University of Texas Southwestern Medical Center, will share the key findings from CORALreef Lipids on enlicitide for LDL-C management. Let's hear from her now.

Dr. Navar:

The most important thing is the efficacy for LDL lowering was about 60 percent. Almost everybody in the trial was on a statin, and the vast majority were on a high-intensity statin. So these are already patients who are very well treated, but still not to goal. We saw also, importantly, placebo-like safety. There were no excess side effects compared with placebo, so this drug was extremely well-tolerated. And then finally, CORALreef Lipids actually followed people for 52 weeks, and we saw sustained efficacy out to a year, which shows that the drug keeps working but also that people are able to keep taking it. And we had an optional open-label extension for people in the trial if they wanted to stay on drug, and almost everybody opted into that, which I think is another reflection of the high degree of tolerability and acceptability of an additional pill for LDL lowering.

We already have a lot of data about this mechanism of lowering LDL, in terms of safety, efficacy, and cardiovascular outcomes. I cannot think of a biological reason why it matters if it's a macrocyclic peptide or a monoclonal antibody that prevents the PCSK9 binding that would affect how this can prevent cardiovascular events. Now, we still have to see the results of the ongoing CORALreef Outcomes trial to check the box. But biologically, we have every reason to believe this is going to prevent cardiovascular events very similarly to what we saw for alirocumab and evolocumab now in three different cardiovascular outcomes trials—SALUS, ODYSSEY, and FOURIER.

The efficacy question isn't really, in my opinion, going to be, does it work? It's going to be, by how much? And basically reinforcing what we already think we know about the biology here. As it relates to the real world, the real key is going to be twofold, and this is something that's affected other lipid-lowering therapies. The first is that to maximize the efficacy, we have to make sure that patients stay on their background therapy. And we've seen with all of the other non-statins that patients sometimes will de-escalate their statin or stop their statin once they get on alternatives, and we have to reinforce to our patients that these are additive. In fact, they're actually synergistic. If we up-regulate the number of LDL receptors with a statin, then we allow them to live longer with PCSK9, they actually work better together.

So the key to real-world efficacy for LDL lowering is patients have to take it as directed, first thing in the morning on empty stomach, and wait 30 minutes. Now, you can have a cup of black coffee or black tea, which I think is critical, at least for me. And you can take it with other medications, as long as the other medications don't say you have to take it alone. Oral semaglutide, for example, you can't take with other meds. But we've studied enlicitide with statins, and we've studied it with narrow therapeutic index drugs. So as long as patients are taking it as directed and they take it every day, which is true for any therapy that you're supposed to take every day, I think we should be able to expect really good long-term adherence.

The other side of the coin, though, is going to be access. And a major driver of discontinuation of both monoclonal antibodies and siRNA therapy is cost and continued need for insurance approval. We're going to have to wait and see how the payer negotiations go, but I'm really optimistic for enlicitide. The sticker price for the drug is far less than the sticker price for other non-statin drugs that aren't generic. My fingers are crossed, and I am hoping that that translates into easier access for us prescribers and we're not jumping through a bunch of prior auth hoops, and hopefully a lower copay for our patients so that they can actually afford it once it's approved.

Announcer:

That was Dr. Ann Marie Navar discussing evidence supporting the approval of enlicitide for LDL-C management. To access this and other episodes in this series, visit Heart Matters on ReachMD.com, where you can be part of the knowledge. Thanks for listening!