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Clinical Evidence for Durable Treatment of nAMD

Announcer:

Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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Dr. Dang:

What is the latest clinical evidence around durable treatment modalities for neovascular macular degeneration? This is CME on ReachMD and I'm Sabin Dang.

Dr. Sridhar:

I'm Jay Sridhar. Great question, Sabin. So, faricimab is this new mechanism of action. We have had intravitreal anti-vascular epithelial growth factor, VEGF, for a long time in the retina space, but now we have faricimab, which has this dual antibody mechanism. It's not only anti-VEGF, it's also an anti-ang2. And because it's targeting 2 distinct disease pathways, one of the goals was to try to come up with more durable therapy for our patients. And, you know, in the phase 3 clinical trials, TENAYA and LUCERNE for wet AMD, the peer data really stressed a really strong durability signal. Sixty-three percent of these patients were q16 weeks and about 80% of them were at least every 12 weeks when you got out to 112 weeks, or again you're talking about 2 years. And if you looked across all the treatment arms, there was comparable visual acuity improvement and central subfield thickness reduction, right? And it was really well tolerated, no safety signals. We do have the long-term extension study which is always important to us when we think about real world. These patients don't just get treatment for 2 years, they're going to have many, many years of treatment. So, this long-term extension study AVONELLE-X, will give us 4 years of data and it really is something that's valuable to look forward to now having this new mechanism of action. It's important to know we also have approved on the market now aflibercept 8 mg, which was the PULSAR 1-year data showed, again, greater durability. So, we're really have better durable agents now, Sabin, than we had historically.

What about the port delivery system and ranibizumab? Ranibizumab is a molecule we've had for a long time, but now this is a new mechanism of delivery. How does that compare in terms of durability?

Dr. Dang:

Great question. And the PDS port delivery system, is a really exciting new platform. To start off, we'll talk about the PORTAL 5-year outcomes. I mean, at the end of the day we want to know is this high-durability treatment, do we see that continued long durability, long mechanism of action over multiple years of treatment, especially because we're committing these patients, Jay, to a surgical intervention. So if you look at the portal 5-year data it is really optimistic-looking data. I mean, we are talking about patients who are in q24-week refills. So these are patients that are really getting their port delivery systems refilled twice a year, and with that, we're able to maintain their visual gains and maintain their visual benefits from this long-lasting anti-VEGF treatment. And, as you have mentioned, we've had ranibizumab for quite some time, so this is a molecule that retina specialists are very familiar with, it's very predictable, we have experience with it. But now we have an alternative means of administering ranibizumab to patients that lasts much longer. So that is exciting, but at the same time, like I alluded to, PDS is a surgical intervention, so there is going to be a different risk profile with the port delivery system that we do have to take into account. So, when we look at the safety outcome data, you know, we are seeing things

that you normally don't see with the standard anti-VEGF intravitreal injection trials.

We have to worry about conj [conjunctival] erosion where the actual implant device becomes exposed. In some cases, these will have to be explanted and you'll have to take the patient back to the operating room. There was a nontrivial amount of vitreous hemorrhage. Now thankfully, these were not visually threatening vitreous hemorrhages. Some of the patients did have to go back for vitrectomy to get these vitreous hemorrhages cleared, but they were able to do well. But that is another concern. The other concern we have with any therapeutic that we're entering the eye with is endophthalmitis, especially now that we have implanted hardware. If patients were to get endophthalmitis from one of these devices, how do we manage that and would that necessitate removing the device, and these are all questions we're still trying to answer. When we look at the clinical trial data, we have a list of site-threatening adverse reactions or events, and thankfully those rates were still relatively low. In this study there was one patient who had a very severe hyphema that was deemed as sight threatening. And we can't talk about PDS without septum dislodgement. As a lot of people know, the PDS has been voluntarily recalled at this time because of this concern for septum dislodgement, so we'll have to see what comes out of all that research to try to rectify that issue, and when and if it will come back to market.

Dr. Sridhar:

Great point, Sabin, and safety is always so important when we start talking about these options for our patients, and septum dislodgement – big issue – voluntary recall, as you mentioned. But it will be important to see what happens in the future. PDS coming back to market, or again, even the second generation. One of the big questions is how do these new durable therapies stack up in the real world? How do they impact visual outcomes in patients? Unfortunately, we don't have time to address that question today, but you can tune into our next episode in the MinuteCME series.

Sabin, thanks so much for joining us today.

Dr. Dang:

Thanks, Jay. See you next time.

Announcer:

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