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Real-World Outcomes with Durable Treatments for Retinal Diseases

Announcer:

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Dr. Weng:

As we've learned from recent experiences, real-world outcomes in large, heterogeneous patient populations are an important part to confirming safety and efficacy of new agents. So what are the real-world outcomes for some of our newly approved agents?

This is CME on ReachMD, and I'm Dr. Christina Weng.

Dr. Borkar:

I'm Dr. Durga Borkar.

The real-world data on faricimab has really been fascinating, particularly taking into context the differences between clinical trial and real-world patients. FARETINA-AMD and -DME are ongoing real-world data studies leveraging data from the IRIS registry that I've been excited to be a part of. These are the largest real-world data studies currently ongoing for faricimab. And what we've seen in this study, where we've looked at over 28,000 eyes in the IRIS registry that were treated with faricimab, it's quite interesting compared to trial. So in FARETINA-DME, we included over 3,000 patient eyes, and what we saw at faricimab initiation was that approximately half of eyes had 20/40 or better vision, which is significantly better than what we see in most clinical trials. Most of them were previously treated; about 75% of the previously treated eyes were actually switched from aflibercept. And what we saw was that after just 4 faricimab injections, although the vision was stable in previously treated eyes, there was significant visual acuity gains in treatment-naïve eyes, and there was treatment extension beyond 6 weeks, after just 1 to 2 injections, in over 60% of both previously treated and treatment-naïve eyes.

We have a significantly larger study population in FARETINA-AMD, consistent with real-world use of faricimab. We had over 17,000 patient eyes in that study, and we saw really similar findings, that nearly half of eyes had 20/40 or better vision. About 2/3 of the previously treated eyes were faricimab switchers, and visual acuity outcomes were fairly similar in terms of what we saw with visual acuity gains. Vision was stable in previously treated eyes, and there was improvement in the treatment-naïve eyes.

What's interesting is that there is a very small group of treatment-naïve eyes in both of these studies, which is of course different than what we saw in the clinical trials, particularly for neovascular AMD. And you know, there have been other studies that have lent a lot of interesting information to the retina community.

TRUCKEE is another interesting real-world, physician-led, multicenter study looking at the real-world efficacy, durability, and safety of faricimab for neovascular AMD, specifically. And there were some great studies that were presented at ASRS. One looked at OCT [optical coherence tomography] parameters, which we haven't yet looked at in FARETINA. And specifically, they looked at intraretinal and subretinal fluid reduction after just 1 injection of faricimab. And you can see across the board, for both treatment-naïve and treatment-experienced patients, including aflibercept-treated eyes, that there was significant fluid reduction seen after just 1 injection. It's

interesting that the treatment-naïve group here is also much smaller than the treatment-experienced group. We've seen that in other studies, as I mentioned.

I think what was really poignant about the TRUCKEE results is that they presented safety data at ASRS as well, and that's been promising. And out of almost 6,000 injections, there were just 4 reported cases of infectious endophthalmitis and 9 cases of other intraocular inflammation, with all of them resolving. And I think what's most important is that they haven't seen any cases of retinal vasculitis or retinal artery occlusion in these studies.

Dr. Weng:

Well, that is surely reassuring that no new safety signals have appeared, although I agree with you, Durga, I think we could benefit from more data on treatment-naïve populations. We also need to further explore and better understand the differences we see between outcomes from clinical trials and those that we see from real-world studies. And I think one of the studies that will help us do that is the VOYAGER study, which is a global, noninterventional, prospective study that will include patients being treated with faricimab or the port delivery system with ranibizumab for wet AMD or DME. And data will be collected per routine clinical practice over a time span of 5 years from enrollment, with a primary objective being change in visual acuity from baseline at 12 months. A number of secondary endpoints will also be evaluated, including the number of treatments, anatomical changes, the presence and the location of fluid, as well as ocular and systemic safety and tolerability.

Dr. Borkar:

That's great. I'm interested to see the results from VOYAGER as we continue to keep an eye out for more data from FARETINA as well. So far no surprises with faricimab.

Dr. Weng:

Absolutely. Well, that's all the time we have for today. Thanks for joining me, Durga.

Dr. Borkar:

My pleasure.

Announcer:

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