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

Who Needs a TKI? Identifying the Right Candidates

Announcer:
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Dr. Goldberg:
This is CE on ReachMD, and I'm Dr. Roger Goldberg. Here with me today is Dr. Christina Weng. Let's get right into today's topic.

Dr. Weng, given ongoing and upcoming phase 3 trial designs for investigational TKIs, which patients are the most likely to benefit from treatment if and when one or more are approved?

Dr. Weng:
Great to be here with you, Roger. Of course, we're all waiting with great anticipation for the readouts from the pivotal trials LUGANO and LUCIA for EYP-1901, as well as SOL-1 and SOL-R for OTX-TKI, to better inform our applications of these 2 leading TKIs if and when they're approved. And let me answer your question by starting off talking about what we know so far. And I think that when I think about the data that we're aware of and the inclusion criteria for these pivotal studies, I think that there are essentially 3 groups of patients who might be excellent candidates for these drugs. The first is those who are not fully responsive to current anti-VEGF therapies. The second are those who are fully responsive to our current anti-VEGF therapies but want to reduce treatment burden, and the third really is treatment-naïve patients.

So essentially that encompasses basically all patients. And I'm saying this based on what we know about the ongoing and prior trials for EYP-1901 and OTX-TKI. Let's look at EYP-1901 first. So the LUGANO and LUCIA trials randomized both treatment-naïve and treatment-experienced wet AMD patients with best-corrected visual acuity between approximately 20/32 and 20/200, and both the EYP-1901 and control arms received 3 monthly loading doses of aflibercept 2 mg, and then the EYP-1901 arm received q6-month treatment, while the aflibercept arm was treated q8 weeks on label. Both of those arms could receive supplemental treatment if criteria were met.

Turning to the OTX-TKI studies, SOL-1 is a superiority study that included only treatment-naïve patients with wet AMD and baseline visual acuity of 20/80 or better. Patients received 2 loading injections of aflibercept, and if they were either approximately 20/20 or had an increase of at least 10 ETDRS letters from screening, they were then randomized to either receive a single injection of either an OTX-TKI or aflibercept 2 mg and then were subsequently followed. And the primary endpoint for that study was at 36 weeks looking at the proportion of subjects with less than a 15-letter loss from baseline. So essentially, the proportion of patients who were able to maintain stable vision.

Contrast that to the sister companion study SOL-R, which is a non-inferiority study that included both treatment-naïve and experienced patients diagnosed with wet AMD within 3 months prior to enrollment. And in that study, patients received 2 loading doses of aflibercept, and then similar to SOL-1, had to either have a visual acuity of approximately 20/20 or a gain of at least 10 ETDRS letters from baseline

in order to proceed to being randomized into 1 of 3 arms, OTX-TKI q6 months, aflibercept 2 mg q8 weeks, or aflibercept 8 mg q6 months, with primary endpoint being mean change and best corrective visual acuity at week 56.

And the readouts, as you know, Roger, for these studies are expected this coming year in 2026, but the bottom line is that a broad range of patients and multiple dosing approaches are being evaluated in these ongoing TKI studies, which will be really informative. The Phase 1 OTX-TKI studies and the phase 1 and 2 EYP-1901 studies have demonstrated the potential of these TKIs to reduce treatment burden for patients. And you've talked a lot about this. When you think about the challenges we have with current wet AMD treatments with adherence, need for patient support systems, the socioeconomic factors, risk for disease progression with delayed or missed visits, you really begin to appreciate what benefits these longer-durability therapeutics like the TKIs could bring.

Dr. Goldberg:
Yeah. I mean, first of all, Christina, that's a tremendous summary. Those are complex clinical trials, and you gave us just an amazing summary of the key components of their designs and how they're going to inform how we use these in patient care. I agree with you. 2026 is going to be super exciting because we're going to learn so much, not just about these specific agents; frankly, we're going to learn a lot about the treatment and management of wet AMD. As you mentioned, the SOL-1 study is a very different type of study than we've ever seen before. I think we're going to learn a lot just about wet AMD overall. When I talk to retina specialists at the meetings, people are excited to have these as part of our arsenal to care for patients with wet AMD and ultimately eventually with DME and diabetic retinopathy.

Well, this has been a great discussion and I'm excited for the continued evolution of the treatment landscape for exudative retinal disease. Thank you so much for listening and, Christina, thanks for joining me.

Dr. Weng:
Thanks.

Announcer:
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