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Redefining Durability in Wet AMD: Insights from the SOL-1 Superiority Trial

Announcer:
You're listening to ReachMD. This medical industry feature, titled "Redefining Durability in Wet AMD: Insights From the SOL-1 Superiority Trial" is sponsored by Ocular Therapeutix.

Andrew Moshfeghi is a consultant for Ocular Therapeutix. The following information discusses OTX-TKI – an investigational product candidate that has not been approved by the FDA or any other regulatory body; safety and effectiveness have not been established.

Here's your host, Dr. Priya Vakharia.

Dr. Vakharia:
This is ReachMD and I'm Priya Vakharia. Today we'll be speaking with Dr. Andrew Moshfeghi about the SOL-1 phase three superiority trial of O-T-X-T-K-I in wet age-related macular degeneration, or wet AMD for short. Dr. Moshfeghi recently gave a presentation titled Redefining the Management of Neovascular AMD on this topic at the VIT Buckle Society.

Welcome to the program, Dr. Moshfeghi.

Dr. Moshfeghi:
Thanks for having me.

Dr. Vakharia:
So first, let's get started. Can you walk us through what is O-T-X-T-K-I and what the SOL-1 study was.

Dr. Moshfeghi:
Sure. So O-T-X-T-K-I is a combination of a hydrogel platform to which tyrosine kinase inhibitor axitinib is slowly released over time with near zero order kinetics after a single intravitreal injection.

And this works intracellularly to have an anti-VEGF effect in diseases such as age-related macular degeneration like we talked about today.

Dr. Vakharia:
In the SOL-1 trial., specifically, how did this look at O-T-X-T-K-I?

Dr. Moshfeghi:
This is a unique trial design, and this was based upon new guidelines from the FDA regarding, you know, what type of studies are going to be allowed, what type of comparatory groups you have to have in order to get certain types of either superiority study or a non-inferiority study.

And our goal was to have a superiority study design. So this was a study with a 36 week primary endpoint, and the goal was to look at the proportion of patients in OTX group versus Aflibercept two milligram group that were able to hold off losing 15 letters of E-T-D-R-S vision over the 36 week endpoint.

And patients were first identified as having 20/80 or better vision at screening. Then they were given two monthly Aflibercept injections. This is to the entire cohort of patients. Then they were brought in for a baseline randomization visit. They had to improve either 10 letters or to basically achieve almost 20/25 vision from that screening visit after exposure to the Aflibercept. If they did, and they had 350 microns or less of central subfield thickness at that point, then they were randomized to either receive an intravitreal injection of O-T-X-T-K-I, or one additional Aflibercept injection of two milligrams Aflibercept. Then there were no additional planned Aflibercept injections for

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the Aflibercept group or for the O-T-X-T-K-I group. Patients were then followed out to the primary endpoint of 36 weeks to see what proportion of them had lost 15 letters.

And if they did, then rescue therapy was eligible with a loss of 15 letters. That was the trigger for getting a rescue therapy with intravitreal Aflibercept two milligrams.

Dr. Vakharia:
Thank you for walking through that. So this was a superiority study and, you know, you just gave this session at the VIT Buckle Society kind of talking about this potential as a treatment for neovascular age-related macular degeneration.

Can you elaborate a little bit more on what other data you presented in the symposium?

Dr. Moshfeghi:
We really looked at a couple things. One was the durability of the treatment, you know, so basically you're just getting that one O-T-X-T-K-I after the loading doses of Aflibercept, and then you're being followed.

We're not used to a patient being able to go, you know, four months, six months, twelve months or longer with just a single intervention of any kind. So, really we wanted to see could we meet that endpoint at Week 36.

We continued to follow patients out to 52 weeks, and what we found was that we were able to do that in a manner that provided a highly statistically significant outcome favoring O-T-X-T-K-I over the Aflibercept two milligrams.

So that was one take home point.

The second take home point was patients who needed rescue treatments, how frequently was that occurring in the O-T-X-T-K-I arm versus the Aflibercept arm? We saw that there was a treatment benefit favoring O-T-X-T-K-I, a retreatment rescue therapy benefit, such that patients who got rescue therapy were getting it 24 weeks sooner in the Aflibercept arm than in the O-T-X-T-K-I arm.

Dr. Vakharia:
So, let's kind of frame this in the context of current treatment. So currently we have anti-VEGFs and we are able, in many instances to extend patients out to 12 or 16 weeks. And so where does O-T-X-T-K-I fit into this treatment algorithm?

Dr. Moshfeghi:
You're right. And you know, every once in a while we can get a patient that can go like, you know, a really long time with no additional treatment. But the problem is we don't know who those patients are when we're first managing those patients. So the goal with drugs like O-T-X-T-K-I, that are under evaluation, is can we use this on everyone and get a more predictable response out to not just like 70% of patients at certain time points, but can we get like, you know, the overwhelming majority of patients to get the desired outcome, desired durable treatment effect with no additional interventions.

Dr. Vakharia:
Another thing you talked about today was vision and CST outcomes. Can you remind the listeners exactly what you talked about and how that could also apply to our patient population?

Dr. Moshfeghi:
Yeah, so central subfield thickness was one of the metrics that we looked at from an anatomic perspective.

And the reason why we like that is that unlike visual acuity, which can be a little bit subjective, the OCT is what the OCT is. And so it's very objective measurement. And so we found that the time to certain thresholds, a 30 micron increase in central subfield thickness, a 75 micron increase in central subfield thickness favored the O-T-X-T-K-I arm compared with Aflibercept arm.

Dr. Vakharia:
So, I mean, that is really cool. So especially, let's, let's hone in on CST.

There's a huge buzz around retinal fluctuation and thickness amplitude. Does this product, in your mind, help with that? You know, we see patients who come in and they swell and they contract and they swell and they contract.

Is this a meaningful treatment option? Potentially, obviously this is not FDA approved yet, but if it gets FDA approval, could this be a potential treatment option specifically in our wet AMD patients to prevent some of those fluctuations?

Dr. Moshfeghi:
Yeah, I mean, I think that's one of our goals is to have more consistent and reproducible and predictable OCT metrics over time, so we're not having these zigzag patterns on OCT central subfield thickness.

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We think that keeping fluid away is more favorable than, you know, allowing it to reaccumulate and then making it go away.

The data are promising with respect to more consistent OCT central subfield thickness over time, as well as macular volume metrics.

Dr. Vakharia:
One aspect observed in the rescue free O-T-X-T-K-I data was the stability of vision and anatomic outcomes through week 36.

From your perspective, how might the predictability and consistency of these measures contribute to the goal of maintaining disease control in wet AMD patients? You know, as we know, these patients have a lot more fluctuation and aren't as compliant in the real world.

So how might this apply to a real-world setting?

In the real world, we're having patients come back at specified intervals, and if they miss the appointment, it might take them a few extra weeks to get back in for another appointment. And with a more long lasting, more durable treatment, hopefully, those missed appointments, those missed visits, those couldn't get back into the doctor's office in a timely manner type of problems will hopefully be mitigated by the longer lasting, durable treatment effect that we get with O-T-X-T-K-I, thus far to date in the clinical trial program.

All right. Most important question. Let's talk about safety.

So can you summarize the safety profile of O-T-X-T-K-I?

So with respect to the most important things, we didn't see any treatment related adverse events with respect to retinal vasculitis, either occlusive or non-occlusive retinal vasculitis. No patient had to exit the study as a result of the study interventions.

Dr. Moshfeghi:
There were really high retention rates in the study in both arms, 94 and 97% respectively, with O-T-X-T-K-I and Aflibercept. And that's one of the highest retention rates at one year than most clinical studies in recent times have had. So, this shows you that it's a tolerable treatment patients return. They're not leaving the study for it. There were some side effects that were noted. So vitreous floaters can be something that a patient brings to your attention. And we anticipate that this would happen around the time of bio reabsorption of the hydrogel carrier for the drug, which tends to occur as you get closer to between like 30 to 40 weeks. That's around the timeframe that the drug is gonna separate from the hydrogel carrier. And around that time, you effectively get a little bit of a burst of free exit then inside the vitreous cavity.

Dr. Vakharia:
So if you could leave our audience with a few key takeaways, what would those be?

Dr. Moshfeghi:
First of all, we wanna say that O-T-X-T-K-I was generally well tolerated in the data that has been received to date, number one.

Number two, high retention rates. Bear that out like we just talked about.

Number three, we're getting a durable and predictable, more predictable I should say, treatment effect both functionally with respect to visual acuity and anatomically with respect to OCT metrics.

Dr. Vakharia:
I mean, those were great takeaways and thank you for sharing those thoughts.

It was really great to speak with you today.

Dr. Moshfeghi:
Likewise.

Dr. Vakharia:
And for ReachMD, I'm Priya Vakharia.

Announcer:
This medical industry feature was sponsored by Ocular Therapeutix. If you missed any part of this discussion, visit Industry Features on ReachMD.com, where you can Be Part of the Knowledge.

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