ReachMD
Be part of the knowledge.

TRANSCRIPT

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/eye-on-ocular-health/evaluating-eyelid-wipes-for-dry-eye-disease-clinical-trial-insights/37276/

ReachMD

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

Evaluating Eyelid Wipes for Dry Eye Disease: Clinical Trial Insights

Announcer:
You're listening to *Eye on Ocular Health* on ReachMD. On this episode, we'll hear from Dr. Houman D. Hemmati, who's an Adjunct Assistant Clinical Professor of Ophthalmology at USC Keck School of Medicine and an attending physician at LA County USC Medical Center. He'll be discussing his study that was presented at the 2025 American Academy of Ophthalmology Annual Meeting, which evaluated the impacts of an eyelid-delivered TRPM8 agonist in patients with dry eye disease. Here's Dr. Hemmati now.

Dr. Hemmati:
This was a proof-of-concept, randomized, vehicle-controlled, double-masked, parallel-study design. It involved 150 subjects around 10 sites in the US. And in that study, we did a seven-day vehicle run with a vehicle eyelid wipe just to be sure that no one is responding somehow to the mechanical action or the vehicle of the product in that eyelid wipe. And then the patients were randomized in a 1:1:1 ratio to placebo eyelid wipe, the 0.1 percent eyelid wipe, or the 0.2 percent eyelid wipe. And from there, they would be using this every day for 28 days, and then they were evaluated once a week for that period of time.

In our study endpoints, we looked at various safety endpoints—such as intraocular pressure and visual acuity—and adverse events, as well as tolerability. For our primary efficacy endpoint, it was the change in unanesthetized Schirmer's test, so looking at tear production but without the placement of an anesthetic drop in the eye. And then additional efficacy endpoints that we looked at were corneal fluorescein staining throughout different zones of the eye. We looked at two different patient-reported outcomes for symptoms. First was the SANDE, which is the System Assessment in Dry Eye, as well as the EDS, the Eye Dryness Score, as well as anesthetized Schirmer and the comfort scale using something called the ASHRAE, which is a seven-point visual analog scale looking at comfort. And based on that, we were able to really assess the product and, and see how was the safety, tolerability, and then efficacy across a variety of very relevant endpoints.

So when we look at the overall results with this novel TRPM8 agonist with an eyelid wipe dosing, we see several conclusions: one, robust efficacy in both sign and symptom in corneal fluorescing staining as well as SANDE, with a trend seen in nonanesthetized Schirmer tear production, and some improvements seen in the eye dryness score. Second, we see a dose response demonstrated across those several endpoints with that 0.2 percent higher dose clearly being the winner across every one of those measures. We had excellent safety and tolerability. Patients really liked it. We weren't seeing patients dropping out of the study due to safety and tolerability issues. And beyond that, this study really validates a novel mechanism of action and, most importantly, a noncorneal delivery route by targeting the eyelid margin for treating dry eye disease by stimulating the TRPM8 afferents at the level of the eyelid margin.

And so the next step in clinical development for IVW-1001 is going to be to go into a phase 3 trial where we do two phase 3 trials with many more patients than we have here, where we focus on the sign and symptom that really showed the greatest efficacy in the current phase 1/2a study, in order to be able to file for an NDA and get approval by the US FDA followed by global regulatory agencies.

Announcer:
That was Dr. Houman D. Hemmati talking about how an eyelid-delivered TRPM8 agonist may help improve outcomes for patients with dry eye disease. To access this and other episodes in our series, visit *Eye on Ocular Health* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!