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Targeting Head and Neck Atopic Dermatitis: Long-Term Outcomes with Tralokinumab

Announcer:
You're listening to *DermConsult* on ReachMD. On this episode, sponsored by LEO Pharma Inc., we'll hear from Dr. Raj Chovatiya. He's an Associate Professor at the Rosalind Franklin University of Medicine and Science and Founder and Director of the Center for Medical Dermatology and Immunology Research in Chicago, Illinois. He'll be discussing the long-term efficacy, safety, and quality-of-life outcomes associated with tralokinumab for head and neck atopic dermatitis. Here's Dr. Chovatiya now.

Dr. Chovatiya:
Head and neck involvement in atopic dermatitis creates a considerable quality of life impact for patients. And recent studies have suggested, in fact, that the majority of patients that have atopic dermatitis actually experience lesions in the head and neck region. And additional data actually says that patients have an immense social stigma, embarrassment, more anxiety and depression, and frankly, they may oftentimes have more severe atopic dermatitis overall if they have head and neck involvement. So it really behooves us to understand our current therapies in this lens and really ask more about our analyses and our ability to understand what atopic dermatitis therapies can do, particularly for such a burdensome area for our patients.

And so we recently undertook and published a post hoc analysis of the ECZTRA 1 and 2 and ECZTEND studies that were looking at tralokinumab versus placebo in the initial phase, and then the extension phase of tralokinumab alone. And tralokinumab, of course, is a blocker of IL-13 that is approved for moderate to severe atopic dermatitis. And the idea here was to really look at individuals that were on continuous tralokinumab therapy over the course of up to a total of 4 years—1-year period of the ECZTRA 1 and 2 studies and 3 years of the ECZTEND period—and understand exactly what happened to the signs and symptoms of their disease in this region.

So it's of course important to note that, on average, patients actually had pretty substantial disease at baseline. And so if you were to break out head and neck from the overall disease severity, we use a score called the EASI, or Eczema Area and Severity Index, that looks at four different body regions. It adds up to 72 as a total, but for the head and neck region, that corresponds to about 7.2 points. So on average, people had a median score of about 3 at baseline, suggesting that there was a lot of signs of disease in this region.

And if you actually track individuals over time and look through the first 52-week period and the additional 3 years ECZTEND period, you actually see a precipitous drop—i.e., an improvement—in their actual head and neck symptoms. So you can see that by the end of a 52-week period, the median number is around 0.4. At the end of 152 weeks after that first 52-week period, the median is around 0.2, suggesting that there was immense improvement for our patients.

And if you actually track the improvement in the head and neck region and look at what happened in the other parts of the body—that would be like the upper limbs, the trunk, the lower limbs—this actually matches quite well, suggesting that there isn't just improvement in the head and neck region, but also improvement across the overall body.

And you might be asking, why is this significant and why does this matter? Well, we know that for many of our patients in the real world, even on systemic therapies, head and neck disease may not be something that is adequately addressed and/or they may actually have flares of their head and neck disease altogether. And when you take a look at some of the more stringent thresholds in this analysis of tralokinumab, for instance, what percentage of people are getting to 75 percent improvement versus getting to total clearance versus maybe just having a 0.1 or less? You see that it's actually, in general, the majority of people hitting clinically meaningful improvement overall in the head and neck region.

This head and neck improvement also corresponded to quality-of-life improvement. So we find that as head and neck disease improves,

there's actually a pretty strong correlation in improvement for the Dermatology Life Quality Index, which is a quality-of-life measure score that we use as well. And in particular, the elements of that quality of life that were important involved how itchy, sore, painful, and stinging the skin had been and how embarrassed or self-conscious people had been because of the skin. So it really highlights probably what people are thinking about when they have involvement in this head and neck region too.

Finally, when patients were actually tracked through this overall period, paradoxical erythema—this idea of redness and/or signs getting worse on treatment in the head and neck region—were very, very rare, if not really uncommon. And generally speaking, for patients—even the rare patients that experienced a transient flare in that region—most of them ended up looking pretty good overall by the end of that time period.

So it's important to note that there's limitations to any post hoc analysis that we might use to really taking a look at how someone may improve, knowing that it's not a randomized, double-blind, placebo-controlled trial. But these types of analyses are so important for our ability to understand what we can do with the medications that we have available to us in the real world, knowing that the head and neck region is very complex. There is a variety of intrinsic risk factors and extrinsic exposure factors—cosmetics, personal products, microbial influences, the environment, UV rays even—it's sometimes not totally predictive what we see in clinical trials in terms of primary endpoints and what we see in the head and neck region.

This type of analysis really allows us to hone in on this body area and suggest that tralokinumab seems to have very remarkable efficacy for improvement of atopic dermatitis in this area. And as our therapeutic landscape becomes more and more complex and we have more options, in the absence of new—let's say—new biomarkers and blood tests and diagnostics that are really going to tell us how to choose the right treatment for the right patient, I think that's maybe ultimately the most important thing here: understanding clinical phenotypes of our patients and really trying to match them to the right treatment and the best therapy that's going to help them improve their atopic dermatitis and ultimately their overall quality of life.

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