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/dermconsult/evaluating-guselkumab-for-pediatric-psoriasis-new-phase-iii-trial-data/32450/

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Evaluating Guselkumab for Pediatric Psoriasis: New Phase III Trial Data

Announcer:
Welcome to *DermConsult* on ReachMD. On this episode, we'll hear from Dr. Amy Paller, who's the Chair of the Department of Dermatology, the Director of the Skin Biology and Diseases Resource-Based Center, and the Walter J. Hamlin Professor of Dermatology at Northwestern University Feinberg School of Medicine. She'll be discussing the results from the phase III PROTOSTAR study on guselkumab in patients with moderate-to-severe pediatric plaque psoriasis. Here's Dr. Paller now.

Dr. Paller:
The treatment landscape for pediatric psoriasis just keeps getting better. I would say that most now favor a medication called ustekinumab because it's not only effective, but it's also only given every three months once it's loaded. The beauty of guselkumab is that it is even more targeted than the ustekinumab. It has even better efficacy based on this new trial in children, but it's also given only every three months, so I think it's going to be the new favorite.

The results of this study of guselkumab for pediatric psoriasis were recently published online in March 2025 in the *Journal of the American Academy of Dermatology*. So the phase III trial was designed in two parts. We had an initial part for patients who were 6 to under 18 in which they would go during the first 16 weeks on either a placebo or on active guselkumab. And there was even an etanercept arm because those in Europe, there's that request to have a comparator. After that 16 weeks, there was a rerandomization based on whether they achieved PASI 90 and what they were on that would allow them to go on to the guselkumab. In parallel, there was also a trial for adolescents that was open label throughout the entire period, and we have now results for 52 weeks for both of these trials. The primary endpoints for these studies varied depending on whether we're talking about the FDA requirement, which was to reach PASI 90, or the EMA requirement, which was a joint endpoint of having an Investigator Global Assessment of clear or almost clear and a PASI 75.

When we look at part one, where there was a placebo-controlled arm, we can see that 66 percent of the children reached an Investigator Global Assessment of clear or almost clear versus 16 percent on placebo. PASI 75 was reached by 76 percent on the active drug versus 20 percent on placebo. And if we're looking at PASI 90, 56 percent reached that versus 16% percent on the placebo. And I should add that was reached by 36 percent of those on the weekly etanercept injections.

Now, we also were able to see what happened with those reaching total clearance, and those numbers, of course, were lower, but nevertheless, a very exciting 39 percent for reaching clear versus 4 percent on placebo. And PASI 100 was 34 percent versus zero, so indeed very close. I should also add that those who were on the active drug had a dramatic reduction in their Children's Dermatology Life Quality Index, and that was a reduction of 7.3 versus 1.9 on the placebo. And 6 is considered clinically meaningful, so certainly achieved with this drug.

We can also look at what happened after that first 16 weeks as well as in the part two open-label study and see that the data just kept getting better from there. And particularly interestingly, in the group that was on the etanercept, at the end of that period of time, they went from 36 percent of them achieving the PASI 90 to in the range of 91 and 96 percent achieving PASI 90. And, of course, very good results as well with those who initially started on placebo or initially started on the guselkumab. So a home run for guselkumab. It seems to be a very safe drug, as is appropriate for a targeted biologic that targets what we think to be a central molecule, which is interleukin-23.

Given that guselkumab has excellent efficacy, no safety signals, and the same three-month interval as the one that we have to give the most infrequently—ustekinumab—I think this is going to be eagerly adopted by specialists as the go-to drug for psoriasis in children

when it becomes available.

A study a few years back showed that the quality-of-life improvement from treating with pediatric psoriasis is significantly better if we can reach PASI 90 than if we can reach PASI 75. That's the new goal, and that's certainly achieved in the vast majority of individuals who are children and adolescents treated with guselkumab.

Announcer:
That was Dr. Amy Paller talking about the phase III PROTOSTAR findings on guselkumab in children with plaque psoriasis. To access this and other episodes in our series, visit *DermConsult* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!