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Examining Delgocitinib for Chronic Hand Eczema: Results from the DELTA Trials

Announcer:
You're listening to *DermConsult* on ReachMD. On this episode, sponsored by LEO Pharma Inc., we'll hear from Dr. Robert Bissonnette, who's a board-certified dermatologist as well as the President and Founder of Innovaderm Research in Montreal. He'll be discussing the phase 3 DELTA 1 and DELTA 2 trial data on the efficacy and safety of delgocitinib cream in adults with moderate to severe chronic hand eczema. Here's Dr. Bissonnette now.

Dr. Bissonnette:
So DELTA 1 and DELTA 2 were two identical trials. These were the pivotal phase 3 studies conducted with delgocitinib in patients with moderate to severe chronic hand eczema. The patient population that was recruited was a patient population suffering from moderate to severe chronic hand eczema that was refractory to topical corticosteroids or patients for whom the use of topical corticosteroids were contraindicated. Patients were randomized in a 2:1 fashion to receive either delgocitinib or vehicle for a period of 16 weeks. The trial was conducted to study both safety and efficacy of topical delgocitinib in this patient population. So in terms of efficacy objective, the primary endpoint was the achievement of IGA, or Investigator Global Assessment, 0 or 1, which means clear or almost clear. Proportion of patients achieving this endpoint was compared for patients randomized to delgocitinib and randomized to vehicle.

One aspect that is very important to note is that this was the first trial ever conducted where a new IGA scale was used where the definition of almost clear was presence of barely perceptible erythema. In other words, a patient showing up at week 16, time of primary endpoint, with a few vesicles left or some scaling left was considered a non-responder.

So in DELTA 1, 487 patients were included, and in DELTA 2, 473 were patients included. As I mentioned before, the randomization scheme was 2:1, so about 66 percent of patients received delgocitinib first and 33 percent of patients received vehicle.

So in terms of efficacy, let's first look at the primary endpoint, which is a proportion of patients achieving an Investigator Global Assessment of clear or almost clear. In DELTA 1, this was achieved by 20 percent of patients randomized to delgocitinib versus 10 percent for patients randomized to vehicle; and in DELTA 2, 29 percent versus 7 percent. And this was obviously statistically significant. As I mentioned before, the IGA scale that was used in this study was a very high-bar IGA. So another way of looking at this efficacy data—and in my personal opinion, it's a better way—is to use this scale called HECSI. So HECSI is a scale that has been extensively used in trials conducted in chronic hand eczema. And it looks at various signs of chronic hand eczema on fingers, fingertips, various areas of hands, and wrists. And the proportion of patients who improve their HECSI score by 75 percent—so 75 percent improvement—was achieved by 49.2 percent and 49.5 percent of patients in both trials. So about half the patients improved by 75 percent or more, versus 23.5 percent and 18.2 percent for patients randomized to vehicle. There was also a significant improvement in terms of itch, in terms of pain, and in terms of quality of life.

In terms of safety, the safety profile was comparable between patients randomized to delgocitinib and patients randomized to vehicle. The most common adverse event was nasopharyngitis, probably not related to the study drug—it was identical in both groups. One aspect that is important is the contact dermatitis adverse event. These adverse events were not higher; in fact, on average, they were lower in patients randomized to delgocitinib. We know that some patients with chronic hand eczema tend to have very sensitive skin, so topical products that tend to sting or burn or irritate the skin are not very well tolerated, and this was not the case with this product. In terms of adverse events related to JAK inhibitors, the serious adverse events that we know have been associated with the class of JAK

inhibitors, these were not seen in this trial.

My personal experience with delgocitinib in the phase 3 program has been very good, so I've seen very fast onset of action. Patients usually within a few weeks see the improvements. Some of my patients even told me that within a few days they see a difference. The other thing that surprised me when I saw the results of the phase 3 program in terms of IGA 0 or 1 is I felt there was a disconnect between what I would see with patients in the trial and the low proportion of patients who achieved IGA 0 or 1 in the 20 to 30 percent range. In fact, I have seen patients who came to me very pleased saying they were clear; they had nothing. But when I looked at their hands, I could still see a few vesicles, scaling, maybe a little bit of hyperkeratosis, and because of that high-bar IGA, I could not consider them responders. So I think the efficacy is higher than what the IGA results told us from that program.

So I think topical corticosteroids will remain first-line therapy. When it doesn't work, when patients have skin atrophy, or when physicians are worried about skin atrophy if they need to use potent or super potent topical corticosteroids long term, I think delgocitinib is a very interesting option. Phase 3 studies have not shown any increase in skin atrophy in patients treated with delgocitinib, and being a pan-JAK, it's not expected to cause that problem that we sometimes see with TCS.

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