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Clinical Data on Switching to Upadacitinib

Dr. Christopher Bunick:
I am Dr. Christopher Bunick, Associate Professor of Dermatology at the Yale School of Medicine in New Haven, Connecticut. I'm privileged to talk to you today about the LEVEL UP clinical trial, particularly focusing in on the SWITCH period of that trial. I was an investigator in the LEVEL UP study. This study had two periods.

Period one was an on-label comparison of upadacitinib and dupilumab for 16 weeks for moderate to severe atopic dermatitis patients. What was really interesting about one was that upadacitinib was superior to dupilumab in achieving the most stringent endpoint ever used in a clinical trial in atopic dermatitis. The composite endpoint EASI 90 and itch 0/1 on an 11-point 0 to 10 scale for measuring itch.

This is really important because the current AHEAD recommendations for managing atopic dermatitis recommend that optimal treatment targets and achieving minimal disease activity require achieving a composite of a clinically observed measure and a patient reported outcome.

And in the case of atopic dermatitis, that is EASI 90 or IGA 0/1 and simultaneously itch 0/1. So to achieve those optimal treatment targets, dupilumab did this about 9% of the patients in the LEVEL UP phase or period one, whereas upadacitinib was around 20% of the patients achieving this endpoint.

One of the biggest questions we have in treating atopic dermatitis is: What do we do if a patient is on a biologic like dupilumab and they're not hitting those treatment targets? The optimal treatment targets that the AHEAD recommendations state you should be aiming for. Well, what we want to do as clinicians is switch them to a therapy that's going to work. What period two of the LEVEL UP trial did, or the SWITCH UP phase of that trial, was it took dupilumab patients that did not respond at week 16 of achieving EASI 75. So patients that did not achieve EASI 75 on dupilumab at week 16 in the period one of LEVEL UP were switched to upadacitinib 15 milligrams daily without a wash-out in the period two or SWITCH UP phase of the trial. Just four weeks into that next 16 weeks of the SWITCH UP period, what was observed was almost two thirds of the patients around 67% of the patients that did not hit EASI 75 on dupilumab at week 16, well, two thirds of them were already hitting EASI 75 in just four weeks after switching to upadacitinib.

Of course, the period two went on longer. It went on to week 32, so an additional 16 weeks. And at week 32, almost 80% of patients that could not hit EASI 75 on dupilumab were now hitting EASI 75 on upadacitinib. The majority of those patients on upadacitinib were at 15 milligrams. Some of them got up titrated after week 20 to upadacitinib 30 milligrams.

What's even more impressive is that if you move towards those stringent endpoints, right, that EASI 90 and itch 0/1, well, after not achieving EASI 75 five dupilumab at week 16, 16 weeks later on upadacitinib 27%, almost one in three patients, were now achieving optimal treatment targets or minimal disease activity as defined by the AHEAD recommendations.

This is a very substantial improvement in the quality of life of atopic dermatitis patients. When you're on a biologic systemic therapy that cannot hit EASI 75, but in just four months, you're now able to take an oral systemic therapy and achieve basically minimal disease activity or hit that optimal treatment target.

Basically what the SWITCH UP phase of the LEVEL UP clinical trial has told us is that if you have a patient that is not hitting either a moderate or optimal treatment targets for moderate to severe atopic dermatitis, there are options out there that can do better. In particular, JAK inhibitors like upadacitinib have been shown to be highly efficacious and highly safe in these atopic dermatitis patients. There's no need to cycle biologics; you can go to a JAK inhibitor and achieve minimal disease activity for your patients.