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/frontlines-psoriasis/long-term-safety-of-ixekizumab-for-psoriasis-a-review-of-key-findings/32428/

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

Long-Term Safety of Ixekizumab for Psoriasis: A Review of Key Findings

Announcer:

You're listening to *On the Frontlines of Psoriasis* on ReachMD. On this episode, we'll hear from Dr. Atul Deodhar, who's a Professor of Medicine and the Medical Director of Rheumatology Clinics at Oregon Health & Science University. Dr. Deodhar is the lead author of a recent study examining the long-term safety of ixekizumab in adult patients with psoriasis, psoriatic arthritis, and axial spondyloarthritis. Let's hear from him now.

Dr. Deodhar:

We wanted to look at three diseases for which ixekizumab has been approved by the FDA: psoriasis, psoriatic arthritis, and axial spondylarthritis. And these are chronic diseases for which patients require long-term and sometimes lifelong treatments. And ixekizumab is a comparatively new drug, which is IL-17A inhibitor, and we wanted to see the long-term safety of ixekizumab since it is likely to be used for a prolonged period of time in these three conditions. So we decided to look at 25 randomized clinical trials. These are all the clinical trials that we could find for psoriasis and psoriatic arthritis and axial spondyloarthritis in which ixekizumab was used. So in total, we had about 22,300 patient years' exposure for this drug in these three different clinical diagnoses so to say.

And what we found out by doing this analysis was that the commonest side effect was infections, and that is not surprising because ixekizumab is a biologic that blocks interleukin-17A. And even though it is targeted, interleukin-17A is used in our daily life to fight infections, mostly fungal infections such as candida, so we were interested in seeing how common the infections are, what types of infections, etc. And to no surprise, the commonest infections actually where some ordinary viral typical infections like nasopharyngitis, upper respiratory tract infections, etc., and this is what we generally find in almost all the studies, so that was not a surprise. Candida, which was a specific infection of interest since IL-17A is a cytokine that we usually use in fighting that infection, that was about close to one to two per hundred patient years. And this "200 hundred patient years" is sometimes difficult for patients to understand, but the way I explain it to them is that "If I treat 100 patients like you over a one-year period, one to two of them will have some candida infection." Also, I want to quickly note here that even though these were the commonest side effects, these were pretty mild to moderate, so patients who actually stopped ixekizumab treatment because of infection was very rare. There were other side effects we were also interested in. We think IL-17A inhibition could lead to inflammatory bowel disease development, and that problem was found to be less than one per hundred patient years—between 0.1 to 0.8—so not even half a patient. I mean, a very low number of patients over 100 patient years developed new inflammatory bowel disease.

So when we compared our results from this pooled safety analysis, we found out that what our previous experience was was very consistent. No new safety signals were found in this pooled large number of patient exposures—so that's 22,300 patient-year exposure—and with all of these 25 studies, we followed until the end of study program. In our experience with ixekizumab after this extensive data analysis, we found out that this is very similar to what we had found originally in the first three months, first six months, and first year of treatment with ixekizumab for psoriasis, psoriatic arthritis, and also for axial spondylarthritis, so no new data emerged. Another thing we found out, interestingly enough, was that year to year we wanted to see what happens between year one and two, two and three, and three and four; if at all, the adverse events became less problematic. However, we didn't really do any statistical analysis, so what I can say is that year to year, there was no difference. So it's not that if you take this drug on a long-term basis, the side effects worsen. That is not the case.

So what our study has shown is that there is more reassuring messaging about the safety of ixekizumab from this very properly done

phase III and phase II clinical trials in three different diseases. So the message to clinicians is to use these numbers in daily clinical practice in their conversations with patients because that is one way of reassuring patients rather than giving a vague risk analysis to the patient about it increasing infection, candida, or IBD. Giving the numbers helps the patient make a shared decision with their doctor whether they should accept this new drug or not.

Announcer:

That was Dr. Atul Deodhar discussing the long-term safety of ixekizumab in patients with psoriasis, psoriatic arthritis, and axial spondyloarthritis. To access this and other episodes in our series, visit *On the Frontlines of Psoriasis* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!