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Kappa-Opioid Settings: Real-World Evidence Insights

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Dr. Sánchez:
Welcome back. This is CME on ReachMD, and I am Emilio Sánchez. Here with me today is Dr. Lucio Manenti, and now we are talking about the new treatment for CKD-aP.

Lucio, what can you tell us about the real-world evidence of the difelikefalin?

Dr. Manenti:
There is a lot of real-world evidence now being published at the moment confirming the efficacy of the difelikefalin. In fact, in many countries, the drug has already been in use for around 2 years. And in other countries, data has been accumulated thanks to the compassionate use program.

For example, an extensive and retrospective, real-world evidence study has been published on patients treated with difelikefalin in a single dialysis provider in the USA.

Efficacy was confirmed in about more than 50% of 715 patients, a lot of patients, and no new safety signals appeared. The study also seems to show, as was already reported in earlier trials, KALM-1 and KALM-2, as we said previously, the effect of the drug is accentuated by continuing the therapy for at least 12 weeks, because some people stopped the treatment before and then had not the opportunity to see that the therapy was completely able to reduce symptoms.

Recently, another Euro study from France confirmed the efficacy of the drug but reported for the first time—this is a relevant question for me—information on what happened when difelikefalin is discontinued, because we have this problem now. We have sometimes a complete response, but we don't know when to stop the treatment. We have a patient without itch, and we have to decide when to stop treatment. And the French group has seen that about 1/2 of the patients show the appearance of intense itching, for which it was necessary to resume therapy in about half the percent of patients.

And in my experience in Italy, my personal experience, I had some problems like that of the French group. When we stopped the treatment, having a complete response for 6 months, the itch returned really, really strong, and I had to repeat the treatment and resume treatment. We don't know when to stop this.

And moreover, recently in Italy, we collected our data about the real-world evidence study in patients treated with a compassionate program, and we have very good results because we observed the clinical response, intended as the reduction of Worst Itch Numerical Rating Scales by at least 3 points, in almost 60% of cases after 4 weeks and more than 80% at 12 weeks. So it was a very relevant response, and the drug was only discontinued in 2 of 20 patients for dizziness and risk for falls.

Dr. Sánchez:
I think that today we have enough data to say that the difelikefalin is a drug which is sufficient to treat chronic kidney disease-associated pruritus, and also that it is safe, but only a small number of patients needs to discontinue this drug due to a precedent.

The unsolved question is when to stop the drug, because we also have, in Spain, the same experience, that when we reduce the dose, or we discontinue it, the itch becomes greater probably than before. So probably, as it is a chronic problem, we need a chronic treatment to manage these patients. Do you agree with me in this?

Dr. Manenti:
Yes, yes, I agree completely.

Dr. Sánchez:
We hope that this information will be useful in practice. Thank you, Lucio, and thank you for listening. Thank you very much.

Announcer:
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