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From Scratch to Strategy: Talking About CKD-aP in Clinical Practice

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Dr. Liossatou:

Hello, everyone. This is a CE with GLC, and I'm Dr. Anastasia Liossatou. Here with me today is Dr. Federico Alberici, and in this episode, we're focusing on how providers may improve engagement with their patients with CKD-associated pruritus regarding their symptoms and quality of life.

So, Federico, can you tell us about the mechanism of action of difelikefalin, and how does that relate to its efficacy?

Dr. Alberici:

So difelikefalin is a relatively recent option for the management of CKD-aP.

The rationale behind the use is that the central pathogenic component for CKD-aP has been found to be an imbalance of activity of the mu and kappa-opioid receptors. And difelikefalin acts as an agonist of the kappa-opioid receptor. What is most important is that this action is restricted to the peripheral nervous system and not to the central nervous system.

So difelikefalin has been tested in the context of CKD-aP in several randomized controlled trials, and there's also a pooled analysis that has been published, with more than 800 patients treated with this drug.

And basically, what has been observed is that after 12 weeks of treatment, patients that received the drug, compared to the patients treated with placebo, underwent a significant improvement of CKD-aP, defined as at least a reduction of at least 3 points of a scale expressing the severity of pruritus, the WI-NRS, the Worst Itch Numeric Rating Scale.

This happened in the context of a drug that proved to be safe. The main adverse events that were observed were diarrhea, dizziness, nausea, vomiting. Those were mainly mild to moderate in nature, tended to improve throughout the time, and were reversible after the drug was withdrawn.

More importantly, there were no signs of action or activity of the drug in the central nervous system, such as abuse potential, euphoria, physical dependence, or withdrawal, signs of withdrawal when the drug was suspended. So this proved to be an effective option.

We are starting to have also real-life data regarding difelikefalin. We have an Italian cohort showing that the drug was effective in

controlling CKD-aP. Around 60% of the patients experienced improvement of the CKD-aP in 4 weeks, and up to 90% improved the symptoms up to 12 weeks. And the safety profile was confirmed also in this context.

It is important to underline that the itch in the context of CKD is a chronic and fluctuating condition. We also have long-term data on patients treated for up to 1 year showing that this is a feasible option in controlling the symptom.

Dr. Liossatou:

Yes, therapies such as difelikefalin, through peripheral kappa-opioid receptor agonism, offer an important targeted option for appropriately selected patients, with evidence supporting meaningful improvements in pruritus intensity and, of course, quality of life, alongside a manageable safety profile when used with proper monitoring.

Thanks for all your time. Thanks for tuning in.

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