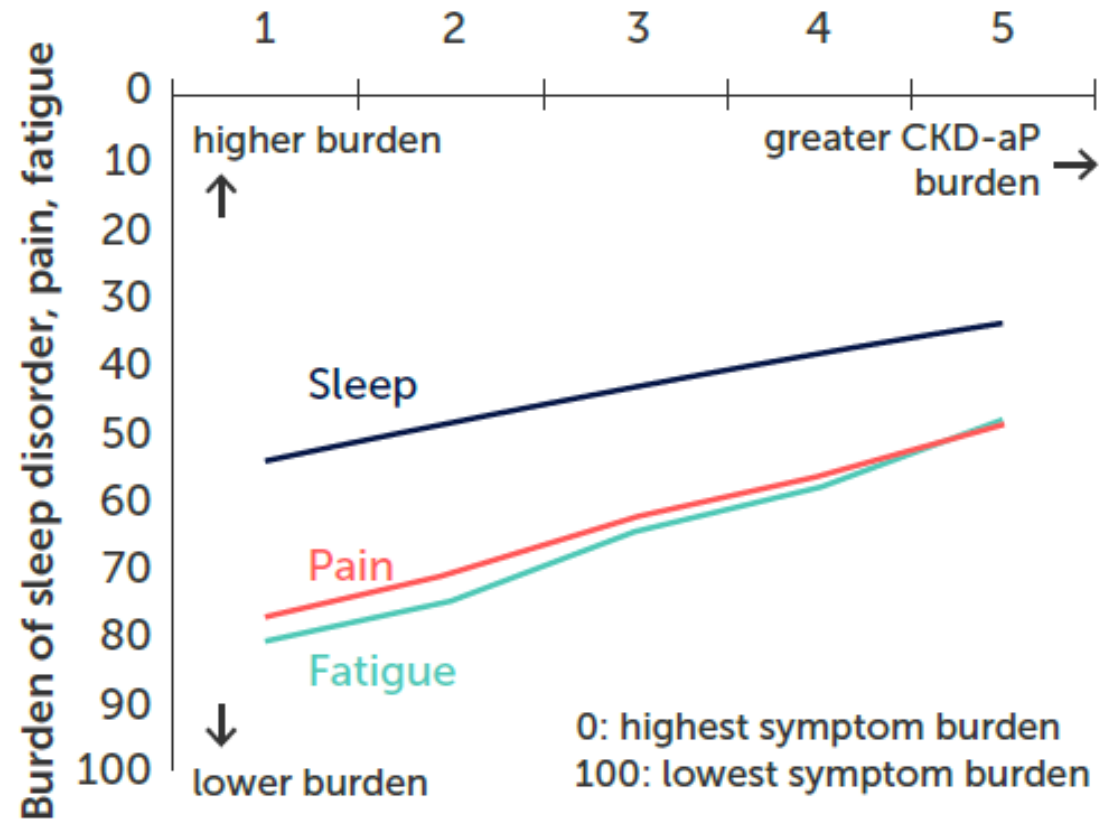


CKD-aP Burden



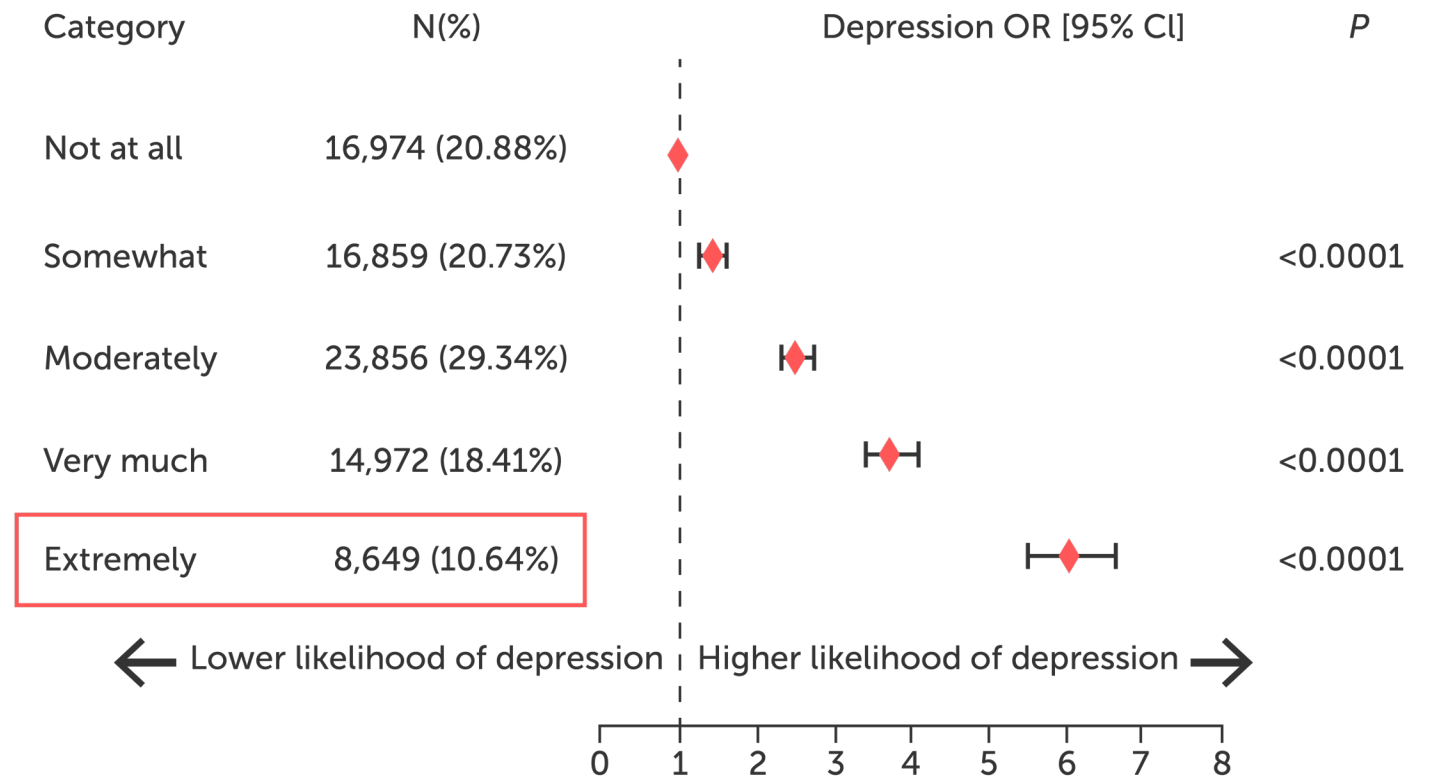
Desai T, et al. Poster presented at: ASN Kidney Week 2023; Philadelphia, PA; November 2, 2023. Abstract TH-PO1138.



Association of Itch Burden and Depression in Patients on Hemodialysis

- Patients who were extremely bothered by CKD-aP had **6x** higher odds of depression when compared to patients “not at all bothered” by pruritus

Association between itch and depression



CKD-aP is associated with ↑ mortality



Difelikefalin



- First and only approved therapy for adult patients with **moderate to severe CKD-aP**
- Peripherally restricted kappa-opioid receptor (KOR) agonist
 - **Does not** cross blood-brain barrier



Difelikefalin

Euphoria

Somnolence

Dependence



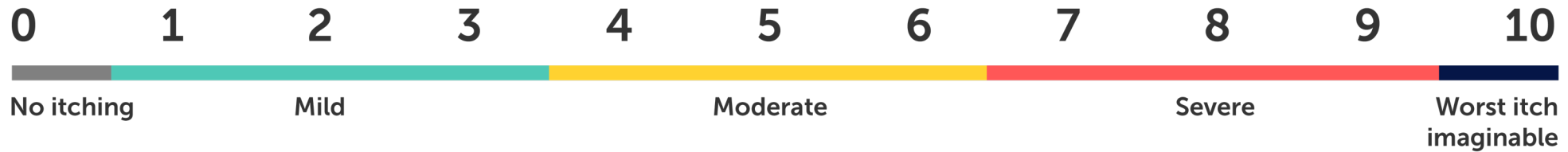
Proactively assess patients for CKD-aP



Worst Itch Numerical Rating Scale (WI-NRS)

Assess Itch Severity

Please rate the worst itch you have felt in the previous 24 hours. Select one option:



Self-Assessed Disease Severity Scale (SADS)

Assess Impact of Itch on QoL

Mild

- I do not generally have scratch marks on my skin
- I do not generally have a problem sleeping because of itching
- My itching does not generally make me feel agitated or sad

Moderate

- I sometimes have scratch marks on my skin
- I sometimes have problems sleeping because of itching
- My itching can sometimes make me feel agitated or sad

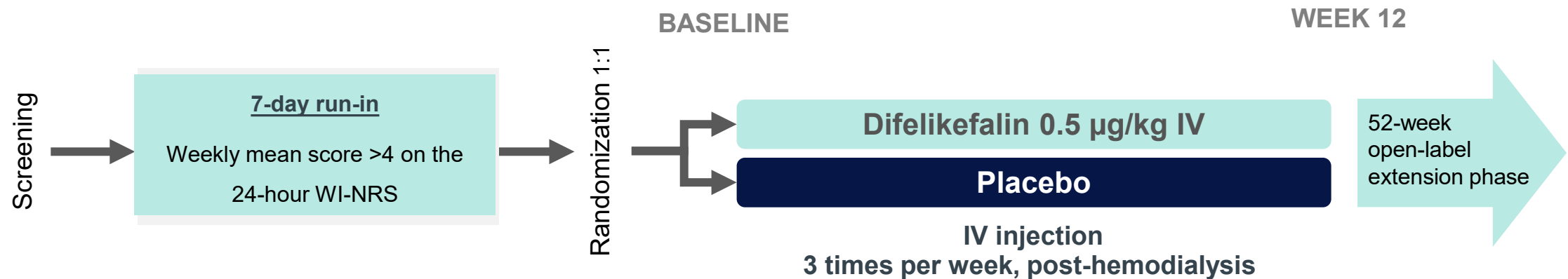
Severe

- I often have scratch marks on my skin that may or may not bleed or get infected
- I often have a problem sleeping because of itching
- My itching often makes me feel agitated or sad



KALM-1 and KALM-2: Pivotal Phase 3 Studies

- Patients ≥ 18 years of age with ESRD and moderate to severe pruritus
 - On hemodialysis (≥ 3 x per week) for ≥ 3 months



KALM-1

US multicenter study

Difelikefalin (n = 189) vs placebo (n = 188)

Completion date: April 2020

KALM-2

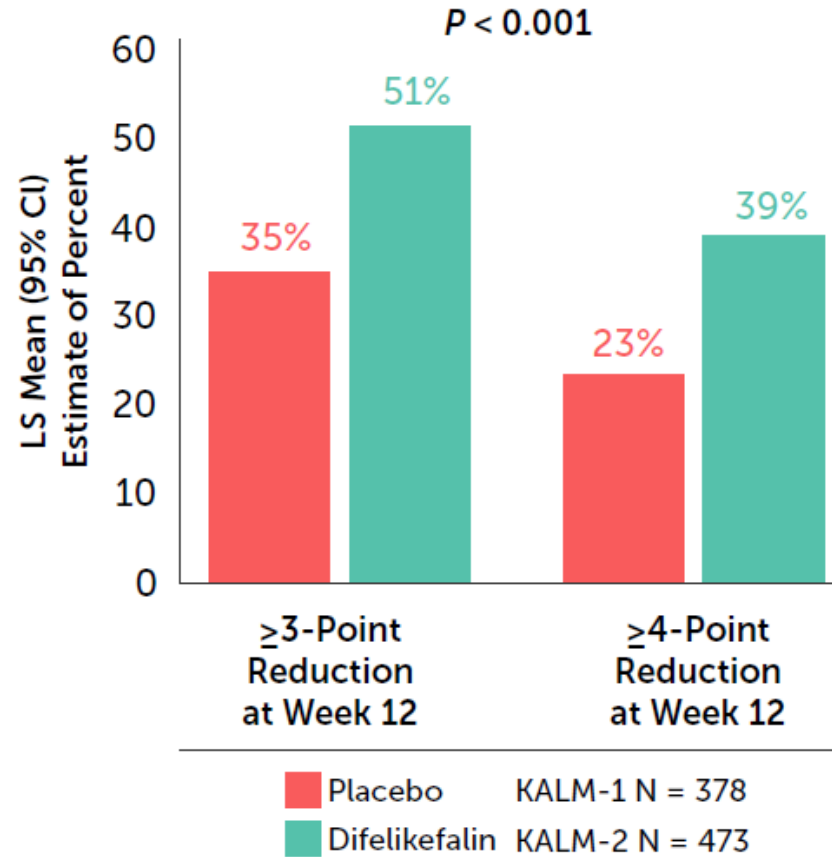
Global multicenter study

Difelikefalin (n = 235) vs placebo (n = 236)

Completion date: March 2020

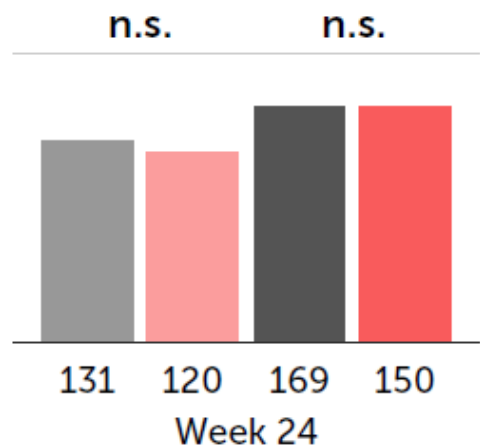


KALM-1 & KALM-2 Pivotal Phase 3 Trials



5-D Itch Total Score After 24 Weeks of Treatment With Difelikefalin

Open-label extension
(all patients on DFK)



■ Pbo/DFK, Baseline WI-NRS < 7 ■ DFK/DFK, Baseline WI-NRS < 7
■ Pbo/DFK, Baseline WI-NRS ≥ 7 ■ DFK/DFK, Baseline WI-NRS ≥ 7

Patients with severe CKD-aP continue to accumulate additional treatment benefit after the initial 12 weeks of treatment with difelikefalin



CKD-Associated Pruritus (CKD-aP)

Like

7



Episodes 1-4 of 4



CME/CE

Why We Should Be PRO Patients With CKD-Associated Pruritus



0.25 credits



CME/CE

Directed Relief in CKD-aP: Linking Targeted Therapy to Clinical Outcomes



0.50 credits



CME/CE

KALMing the Itch: Improving QoL in Patients with CKD-aP



0.25 credits



CME/CE

Separating Fact from Fiction: The Realities of CKD-aP



0.25 credits

