New formulation of FDA-approved drug shows encouraging results for treating a common itch condition

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Notalgia paresthetica—a nerve disorder characterized by a persistent itch in the upper back—is a common and underdiagnosed condition

worldwide. To date, there are no FDA-approved treatments specifically targeting this disorder.

But a new study, published in the *New England Journal of Medicine*, suggests that patients experiencing the moderate-to-severe itching associated with the disorder could potentially get relief with oral difelikefalin. The research was led by investigators at the Icahn School of Medicine at Mount Sinai.

Currently, difelikefalin—a selective kappa-opioid receptor agonist—is only FDA-approved as an injection for the treatment of moderate-to-severe itching associated with chronic kidney disease in adults undergoing hemodialysis.

"For those who experience chronic itch of any kind, relief can sometimes seem unattainable," said principal investigator Brian S. Kim, MD, MTR, FAAD, the Sol and Clara Kest Professor of Dermatology, Vice Chair of Research, and Director of the Mark Lebwohl Center for Neuroinflammation and Sensation at Icahn Mount Sinai. "In this Phase 2 trial, treatment with difelikefalin resulted in a reduction in the intensity of itch in patients with notalgia paresthetica."

In the double-blind, placebo-controlled trial, patients with moderate-to-severe itching from notalgia paresthetica were randomly assigned in a 1:1 ratio to receive oral difelikefalin 2 mg or a placebo twice daily for eight weeks. The primary outcome was the change over eight weeks in the weekly mean of the daily Worst Itch Numeric Rating Scale, in which 0 is "no itch" and 10 is "worst itch imaginable." Secondary clinical outcomes were itch-related quality-of-life and itch-related sleep measures.

Of 126 enrolled patients, 62 were assigned to receive difelikefalin and 63 to receive placebo. The baseline mean score on the Worst Itch

Numeric Rating Scale was 7.6 (severe itch) in each group. The reduction from baseline in the worst itch score at week eight was 4.0 points in patients receiving difelikefalin versus 2.4 points for patients receiving placebo. Secondary outcomes were generally not supportive of the primary analysis. Headache, dizziness, constipation, and increased urine output occurred with difelikefalin.

Larger trials are needed to better assess the efficacy and safety of difelikefalin in notalgia paresthetica. If progress continues in a Phase 3 clinical trial, this medication would be the first FDA-approved drug specifically for people with notalgia paresthetica.

"The encouraging results achieved in this trial could reenergize the field and mark an important step toward improving symptoms of itch for patients with notalgia paresthetica," said Dr. Kim, senior author of the paper, titled "Phase 2 Trial of Difelikefalin in Notalgia Paresthetica."

Additional co-authors are Mark Lebwohl, MD (Icahn Mount Sinai); Robert Bissonnette; (Innovaderm Research), and Kristine Nograles, Catherine Munera; Nilam Shah; Alia Jebara; Josh Cirulli; Joana Goncalves; all with Cara Therapeutics, Inc., the manufacturer of difelikefalin.

More information: Phase 2 Trial of Difelikefalin in Notalgia Paresthetica, *New England Journal of Medicine* (2023).

The trial is registered on ClinicalTrials.gov (NCT04706975).

Provided by The Mount Sinai Hospital

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