

EpiCeram Cream Alone Clears Atopic Dermatitis

BY BRUCE JANCIN
Denver Bureau

KYOTO, JAPAN — Topical EpiCeram is an effective stand-alone therapy for moderate to severe pediatric atopic dermatitis, according to results of a clinical trial.

This physiologic skin barrier repair cream proved itself the equal of fluticasone propionate cream (Cutivate) in a 113-patient multicenter randomized head-to-head comparison, Dr. Jeffrey L. Sugarman reported at an international investigative dermatology meeting.

The observed improvement with EpiCeram in clinical disease severity scores was not as fast as with the mid-strength topical steroid. However, by the

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conclusion of the 4-week, investigator-blinded trial the two groups showed statistically and clinically similar gains in the Scoring Atopic Dermatitis (SCORAD) index, itching scores, and sleep habits,

said Dr. Sugarman, a dermatologist in private practice in Santa Rosa, Calif., and at the University of California, San Francisco.

"I think EpiCeram is an important advance in the management of atopic dermatitis," he said in an interview at the meeting of the European Society for Dermatological Research, the Japanese Society for Investigative Dermatology, and the Society for Investigative Dermatology.

"It's a well-thought-out barrier cream that utilizes our current understanding of the skin barrier in atopic dermatitis in its design and formulation. Since it is steroid-free and calcineurin inhibitor-free, it is inherently safer than these conventional treatments," the dermatologist added.

Indeed, EpiCeram is emblematic of a new paradigm in atopic dermatitis therapy that is based upon targeted, disease-specific lipid replacement, with a resultant marked reduction in the need for topical steroids or immunomodulators. The aim is to repair defective skin barrier function.

This is in line with current thinking regarding the pathogenesis of atopic dermatitis, which holds that defective barrier function is the driver of disease activity rather than a consequence of an underlying immunologic defect, Dr. Sugarman continued.

The 113 participants in the clinical trial ranged in age from 6 months to 18 years. From a mean baseline SCORAD of 36, the EpiCeram-treated group showed a 47% improvement after 2 weeks and a 57% improvement after 4 weeks. The 4-week gain was statistically similar to the mean 69% improvement after 4 weeks of fluticasone, although the mean 61% im-

provement in SCORAD after 2 weeks of fluticasone was significantly better than with EpiCeram at that time point.

After 2 weeks of twice-daily therapy, only 4% of patients in the EpiCeram group showed a greater than 75% improvement in SCORAD scores, compared with 20% on fluticasone. By 4 weeks, 21% of EpiCeram-treated patients had exceeded this threshold, similar to the 26% rate in the fluticasone group.

Pruritus scores improved from a mean baseline of 6.1 on a 10-point scale to 3.5 with EpiCeram and 3.7 with fluticasone after 4 weeks.

Sleep habits also improved significantly from a mean baseline of 3.5 on a 10-point scale to 2.6 with EpiCeram and 2.8 with fluticasone.

The study was sponsored by Ceregenix Corp., which has received Food and Drug Administration marketing approval for EpiCeram. Dr. Sugarman indicated he

has no financial relationship with the company.

Ceregenix has granted exclusive EpiCeram distribution and marketing rights in the United States to Dr. Reddy's Laboratories Ltd., which plans to launch the prescription cream this fall.

EpiCeram is a combination of ceramides, cholesterol, and fatty acids designed to correct the reduction in these skin barrier lipids which is a hallmark of atopic dermatitis. ■

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