New topical agents for acne are rolling out

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EXPERT ANALYSIS FROM SDEF HAWAII DERMATOLOGY SEMINAR

WAILEA, HAWAII – The Food and Drug Administration’s approval of adapalene gel 0.1% as an over-the-counter treatment for acne is a potential game changer that could lead to revision of guideline-recommended treatment algorithms, according to Lawrence F. Eichenfield, MD.

In addition to discussing the implications of the FDA’s unprecedented approval of a full prescription-strength topical retinoid for OTC use, he highlighted other developments in topical therapy for acne, including the 2016 approval of dapsone 7.5% gel, as well as several agents with novel mechanisms of action now wending their way through the developmental pipeline.

In announcing approval of adapalene gel 0.1% as an OTC product, the FDA cited as a major factor in the regulatory decision the opportunity to afford acne patients greater access to retinoid therapy. The drug is now on pharmacy and supermarket shelves, marketed by Galderma Laboratories under the brand name Differin gel 0.1% for once-daily application by patients aged 12 years and older at a cost of $20-$28 for 45 g.

“This development could be very interesting from an access standpoint and in terms of how physicians write prescriptions for retinoids,” said Dr. Eichenfield, professor of dermatology and pediatrics at the University of California, San Diego, and chief of pediatric and adolescent dermatology at Rady Children’s Hospital–San Diego.

“We know that with other retinoids access is an issue. In Southern California, for example, we have strong pharmacy benefits managers for the insurance companies, and they’re very restrictive. It seems like every 3 months they change the tiering of the different retinoids. It’s something we have to work on to get our patients a fair price,” he said at the Hawaii Dermatology Seminar provided by Global Academy for Medical Education/Skin Disease Education Foundation.

Dapsone gel, 7.5%, marketed as Aczone gel, 7.5%, by Allergan, is a once-daily reformulation of the older 5% product administered twice daily. It received FDA approval for use in patients aged 12 years and older based on two 12-week, double-blind, placebo-controlled randomized trials totaling more than 4,300 acne patients. The studies showed the stronger once-daily product was extremely well tolerated, with application site dryness and itching rates similar to those with placebo. In terms of efficacy, a Global Acne Assessment Score of 0 or 1 with at least a 2-grade improvement was achieved in 30% of patients assigned to dapsone gel, 7.5%, compared with 21% of vehicle-treated controls.

Dr. Eichenfield was the lead investigator in a recently published positive phase IIb, randomized vehicle-controlled study of a topical nitric oxide-releasing agent for acne known for now as SB204 (J Drugs Dermatol. 2016 Dec 1;15[12]:1496-502). The product has both antimicrobial and anti-inflammatory properties, bacteria don’t develop resistance to it, and there is no significant systemic absorption.

He noted, however, that in a recent press release the product’s developer, Novan, reported mixed results in two parallel pivotal phase III clinical trials totaling more than 2,600 patients aged 9 years and older with moderate to severe acne. One of the studies was positive for all three coprimary endpoints, but the other trial showed a statistically significant benefit for only one of the three endpoints.

“I haven’t seen the data yet. We’ll have to wait and see whether this agent continues to go forward,” Dr. Eichenfield said.

In its press release, Novan stated that the company believes “its cash on hand is sufficient to fund operations at least through the end of 2017, of which the allocation of capital will be dependent upon further assessment of the SB204 phase III trial results.”

DRM01 is a novel topical inhibitor of acetyl coenzyme-A carboxylase, an enzyme involved in synthesis of the fatty acids that are an essential component of sebum. A phase IIb randomized trial in 420 adult acne patients yielded positive results, according to Dermira, which is developing DRM01. The company plans to begin a pivotal phase III trial in the first half of this year.

Another investigational topical acne therapy to keep an eye on is cortexolone. This peripherally selective antiandrogenic agent is under development by a company called Cassiopea.

Dr. Eichenfield’s financial disclosures included serving as an investigator for Novan, Regeneron, Galderma, and Astellas Pharma US, and as a consultant for Galderma, Genentech, Janssen, Lilly, Otsuka, and TopMD.

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