Safety of Solaraze for Actinic Keratosis Confirmed

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AMSTERDAM — Diclofenac 3% gel was well tolerated and showed an excellent safety profile for treatment of multiple actinic keratoses in a postmarketing safety surveillance study.

The study conducted in 140 primary care practices in the U.K. showed no severe treatment-related adverse events in 450 treated patients. The most common adverse events were mild to moderate dry skin, itching, and redness, each occurring in 16%–20% of patients, Dr. Ron Higson said at the 11th World Congress on Cancers of the Skin. Severe versions of these side effects occurred in fewer than 4% of patients.

Participants in this observational study applied diclofenac 3% gel (Solaraze) twice daily for 12 weeks to areas of actinic keratoses (AKs) in accord with the product labeling. The topical nonsteroidal anti-inflammatory drug is licensed for treatment of AKs in the United States, United Kingdom, and some other European countries. Patients were assessed during office visits at baseline and at weeks 6, 12, and 16.

There was also a secondary efficacy end point consisting of change over time in the longest AK axis from each patient’s three largest AKs. The mean reduction in the size of AKs on the head, face, or neck was 2.8 mm at week 6 and 6.4 mm at the week 16 follow-up visit, Dr. Higson of Clitheroe (U.K.) Health Centre said at the congress.

Dr. Eggert Stockleth, director of the skin cancer center at Charité University Hospital, Berlin, said diclofenac gel’s two major advantages are its safety and the fact that it treats visible AK lesions as well as “field cancerization,” the underlying dysplasia that gives rise to new AKs and eventually to skin cancers.

The congress was cosponsored by the Skin Cancer Foundation and Erasmus University, Rotterdam, the Netherlands. Shire Pharmaceuticals funded the study.

Continued from previous page