

3M Pharmaceuticals Obtains FDA Approval for First Immune Response Modifier to Treat Actinic Keratosis

Patient-applied Aldara Cream clears precancerous skin lesions

According to the American Academy of Dermatology, actinic keratosis (AK) affects as many as 10 million Americans each year. Caused by chronic sun exposure, actinic keratoses are precancerous skin lesions, many of which can occur on the face and scalp.

3M announced today the U.S. Food and Drug Administration (FDA) has granted marketing approval for Aldara (imiquimod) cream, 5%, a topical prescription treatment for clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adults. Aldara cream is the first immune response modifier (IRM) approved for AK.

"Aldara's approval for actinic keratosis represents an important addition to current treatment approaches," stated Barry Labinger, division vice president, 3M Pharmaceuticals Division. Labinger also confirmed that the FDA currently is reviewing the sNDA (supplemental new drug application) for Aldara cream in the treatment of superficial basal cell carcinoma, a common form of nonmelanoma skin cancer.

Clinical trials demonstrated that most patients treated with Aldara cream achieved clearance of 75 percent or more of their AK lesions, and nearly half experienced complete clearance.

The FDA's approval for AK reinforces 3M's confidence in the potential of the company's IRM compounds, according to Labinger. "We look forward to expanding the IRM portfolio to treat a variety of diseases," he said.

Clinical Studies

The FDA's approval of Aldara cream for AK is based on positive results from two double-blind, randomized, placebo-controlled clinical trials involving 436 patients with multiple AK lesions. Patients were treated with Aldara cream or placebo twice a week for 16 weeks. Nearly half of the patients treated with Aldara cream achieved complete clearance of all lesions compared to only 3 percent in the placebo group. A majority of patients experienced lesion clearance of 75 percent or more.

The clinical studies also revealed another important feature of Aldara cream. Among patients treated with Aldara cream, a number of previously undetectable lesions appeared and cleared during treatment.

"Recent studies suggest that chronic sun exposure may cause immunosuppression in the skin," stated lead investigator Mark G. Lebwohl, M.D., FACP, professor and chairman, Department of Dermatology, Mount Sinai Medical Center, New York, N.Y. "Aldara, an immune response modifier, is an exciting treatment advance for patients with AK."

The most frequently reported adverse reactions were local skin reactions, including erythema, flaking/scaling/dryness, scabbing/crusting, edema, erosion/ulceration, weeping/exudates, and itching/ burning at the application site. Only 2 percent of patients reported pain at the lesion site. While 16 percent of patients had a rest period during treatment, only 2 percent discontinued treatment due to local skin or application-site reactions.

About Actinic Keratosis

Actinic keratosis appears as rough, red, scaly patches, or crusts on the skin. AK lesions usually measure less

than one quarter inch in diameter and more than 80 percent of lesions occur on the upper limbs, head and neck. Individuals with fair skin, light hair and light-colored eyes are at greatest risk for AK. Because AK is caused by cumulative sun exposure, it can take years to develop. The condition usually appears first in older people, although cases have been reported in people in their 40s.

Common AK treatments include cryotherapy (freezing), excisional surgery, electrodesiccation (burning) and curettage, lasers, topical chemotherapy and photodynamic therapy.

For more information about Aldara cream, AK or for full prescribing information, call 1-877-4-AK-NEWS, or visit www.aldara.com.

About 3M Pharmaceuticals

3M Pharmaceuticals, a division of 3M Health Care, develops, manufactures and sells branded prescription drug products related to dermatology, women's health, sexual health, cardiology and respiratory medicine. Additional information is available at www.3M.com/pharma. 3M Health Care, the largest of 3M's seven business segments, is dedicated to improving the practice, delivery and outcome of care in medical, dental, pharmaceutical, health information systems and personal care markets.

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3M, St. Paul Media Contacts: John Cornwell, 651-733-7698 or Theresa Kim, 212-856-8550

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