

3M Pharmaceuticals Announces Long-term Clinical Benefits of Aldara Cream for Actinic Keratosis

- Majority of Patients Had No Recurrence or New AK Lesions One and One-half Years Post-treatment -

According to a recent study published in the June issue of Dermatologic Surgery, prescription Aldara (imiquimod) cream, 5% delivers long-term clinical benefits in the treatment of actinic keratosis (AK), a precancerous skin condition caused by chronic sun exposure. Led by an investigator at the University of Minnesota, the study showed 75 percent of patients treated with Aldara Cream three times per week, and nearly 60 percent treated two times per week, continued to demonstrate complete clearance of AK after a follow-up period of 12 to 18 months. The first immune response modifier (IRM) approved for AK, Aldara cream stimulates the skin's immune response, which may help decrease formation of recurrent or new AKs.

The American Academy of Dermatology estimates as many as 10 million Americans are affected by AK. If left untreated, AK may develop into squamous cell carcinoma (SCC), the second leading cause of death from skin cancer in the United States.

"This study confirms my belief in Aldara cream and its potential to proactively treat certain types of AK and, more importantly, decrease the possibility for recurrence," said Dr. Peter K. Lee, lead investigator, University of Minnesota.

Dr. Lee also noted that treatment with Aldara cream for both clinical and subclinical AK lesions could reduce the number of physician visits and treatments, as well as the potential for developing SCC.

The longitudinal, observational study followed Phase III clinical trials which showed Aldara cream to be safe and effective in the treatment of AK. Specifically, only 24.7 percent of those treated three times per week and 42.6 percent treated two times per week showed a recurrence or new lesion in the original treatment area up to 18 months post-treatment. The median number of AK lesions present for both groups was one lesion in the previously treated area, compared to a median of six lesions at baseline in Phase III studies. Of the 15 patients in the placebo group, nearly half (46.7 percent) had a recurrence of AK.

Early last year, the U.S. Food and Drug Administration approved Aldara Cream as a topical prescription for certain types (clinically typical, nonhyperkeratotic, nonhypertrophic) of AK on the face or scalp dosed two times a week. And for the treatment of biopsy-confirmed, primary superficial basal cell carcinoma (sBCC) used five times a week. Aldara cream is the first prescription therapy in over a decade approved for the treatment of sBCC, a type of nonmelanoma skin cancer.

In Phase III pivotal trials, most patients treated with Aldara cream achieved clearance of 75 percent or more of their AK lesions, and nearly half experienced complete clearance. 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. In Phase III sBCC pivotal studies, 82 percent of patients treated with Aldara cream achieved histological (confirmed through biopsy) clearance and 75 percent achieved composite clearance, defined as clearance confirmed by both biopsy and visual inspection.

In AK clinical studies, the most common side effects involved skin reactions in the application area. These included redness, swelling, erosions, weeping, scabbing, itching and burning. Most skin reactions were rated mild to moderate.

In sBCC clinical studies, the most frequently reported adverse reactions were local skin reactions, including

flaking/scaling, induration, edema, erythema, scabbing/crusting, erosion, and itching and burning at the application site. These local skin reactions generally decrease in intensity or resolve after cessation of Aldara cream therapy. Overall, only 2 percent of patients discontinued therapy due to local skin/application-site reactions.

Exposure to sunlight (including sunlamps) should be avoided or minimized during use of Aldara cream because of concern for heightened sunburn susceptibility. Patients should be warned to use protective clothing (hat) when using Aldara cream.

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.

Since the effect of chronic ultraviolet exposure has a field effect, causing genetic damage to widespread areas of the skin, AK can be considered a chronic disease with most patients developing new or recurrent lesions over time. Since most AK therapies do not address the underlying cause of the disease, they do not provide any long-lasting benefit to the patient beyond the initial clearance of visible lesions.

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

About Superficial Basal Cell Carcinoma

According to the American Cancer Society, more than 1 million new cases of nonmelanoma skin cancer occur in the United States each year. Basal cell carcinoma (BCC) affects an estimated 800,000 Americans each year, and there are four types of BCC comprised of superficial, nodular, pigmented, ulcerating or sclerosing types.

Individuals with fair skin, blond or red hair and blue or green eyes, and those living in sunny climates are at the greatest risk for developing sBCC. Usually, sBCC develops on sun-exposed areas of the body. Superficial BCC can appear as red, finely wrinkled, scaly patches that occasionally have a fine, pearly border.

Common treatments for sBCC include surgical excision, cryosurgery (freezing), curettage (scraping) and electrodesiccation (burning).

About 3M Pharmaceuticals - Part of the 3M Health Care Family

3M Health Care, the largest of seven major 3M businesses, is dedicated to improving the practice, delivery and outcome of care in medical, dental, pharmaceutical, health information and personal care markets. 3M Pharmaceuticals, part of the 3M Health Care family, develops, manufactures and sells branded prescription drug products for dermatology, women's health, sexual health, cardiology and respiratory medicine. More information about AK and Aldara cream is available at www.treatAK.com.

About 3M - A Global, Diversified Technology Company

Every day, 3M people find new ways to make amazing things happen. Wherever they are, whatever they do, the company's customers know they can rely on 3M to help make their lives better. 3M's brands include Scotch, Post-it, Scotchgard, Thinsulate, Scotch-Brite, Filtrete, Command and Vikuiti. Serving customers in more than

200 countries around the world, the company's 67,000 people use their expertise, technologies and global strength to lead in major markets including consumer and office; display and graphics; electronics and telecommunications; safety, security and protection services; health care; industrial and transportation. For more information, including the latest product and technology news, visit www.3M.com.

Aldara, Scotch, Post-it, Scotchgard, Thinsulate, Scotch-Brite, Filtrete, Command and Vikuiti are trademarks of 3M.

3M, St. Paul
Sue Bender, 212-856-8705 or Glenn Carter, 651-737-0687

<https://news.3m.com/2005-06-20-3M-Pharmaceuticals-Announces-Long-term-Clinical-Benefits-of-Aldara-Cream-for-Actinic-Keratosis>