3M Pharmaceuticals Granted FDA Approval for Aldara - imiquimod- Cream, 5% to Treat Superficial Basal Cell Carcinoma, a Form of Nonmelanoma Skin Cancer

Second New Indication Received in Four Months

3M announced today that the U.S. Food and Drug Administration (FDA) has approved the first prescription therapy in nearly a decade for the treatment of superficial basal cell carcinoma (sBCC), a type of nonmelanoma skin cancer. Aldara(TM) (imiquimod) Cream, 5%, a topical immune response modifier, is now available to treat biopsy-confirmed, primary sBCC in adults with normal immune systems.

In March, Aldara Cream received FDA approval for the treatment of certain types of actinic keratosis (AK) (clinically typical, nonhyperkeratotic, nonhypertrophic) on the face or scalp in adults with normal immune systems. AK is a precancerous skin condition with lesions often occurring on the face or scalp. Both AK and sBCC are skin conditions caused by chronic sun exposure.

"The approval of Aldara for superficial basal cell carcinoma, along with the recent actinic keratosis approval, reflect the increasing importance of Aldara for dermatologists in the treatment of serious dermatologic conditions," stated Barry Labinger, division vice president, 3M Pharmaceuticals.

3M is developing multiple immune response modifier compounds for a variety of diseases.

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.

"It is imperative for the medical community to continue striving toward new and better options for treating nonmelanoma skin cancer," stated Darrell Rigel, M.D., Clinical Professor of Dermatology, NYU School of Medicine. "Aldara Cream, an immune response modifier, is a unique, nonsurgical treatment advance for patients with certain types of BCC. It is already being used successfully in treating actinic keratosis," he said.

Clinical Studies

The FDA approval of Aldara Cream for sBCC is based on results from two double-blind, placebo-controlled clinical trials involving 364 patients with primary sBCCs. Patients with one biopsy-confirmed sBCC tumor were enrolled and randomly assigned to receive Aldara Cream or placebo cream once daily, five times a week for six weeks.

Clinical studies showed that 75 percent of patients treated with Aldara Cream achieved composite clearance compared with two percent in the placebo group. In addition, the histological (confirmed through biopsy) clearance rate was 82 percent for patients treated with Aldara Cream compared to three percent in the placebo group. Histological and composite clearance rates were assessed at 12 weeks posttreatment.

Aldara Cream is indicated for the treatment of sBCC tumors with a maximum diameter of 2.0 cm, on certain areas of the body, only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured. The safety and effectiveness of Aldara Cream have not been established for other types of basal cell carcinomas, including nodular, morpheaform (fibrosing or sclerosing) types.

In 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 two percent of patients discontinued therapy due to local skin/application-site reactions.

About Superficial Basal Cell Carcinoma

According to the American Cancer Society, more than one 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 Actinic Keratosis

According to the American Academy of Dermatology, AK affects as many as 10 million Americans each year. Caused by chronic sun exposure, AK is a precancerous skin condition, which often occurs on the face and scalp.

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), surgical excision, electrodesiccation (burning), curettage (scraping), lasers, topical chemotherapy and photodynamic therapy.

For more information about Aldara Cream, sBCC, AK or for full prescribing information, visit www.Aldara.com.

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. Additional information is available at www.3M.com.

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