3M Submits Supplemental New Drug Application to FDA for Aldara Cream for the Treatment of Actinic Keratosis

First Immune Response Modifier to Seek Indication to Treat Common Precursor to Skin Cancer -

3M announced today that the company has submitted a supplemental new drug application (sNDA) with the U.S. Food and Drug Administration (FDA) to market Aldara cream, an immune response modifier (IRM), for the treatment of actinic keratosis (AK). AK is a common, potentially serious skin condition affecting as many as 10 million Americans each year. Aldara, currently the leading prescription treatment for external genital and perianal warts, is the first IRM application submitted for the AK indication.

"We are very encouraged by recent clinical data which support the use of Aldara in treating patients with AK," said Barry Labinger, vice president, 3M Pharmaceuticals. "Aldara represents an entirely new approach to treating this precursor to skin cancer." Labinger confirmed that 3M is also on target to submit an sNDA for Aldara in the treatment of superficial basal cell carcinoma, a common form of non-melonoma skin cancer. 3M continues to build a pipeline for new IRM molecules for a broad range of indications.

The Aldara sNDA is based on positive results from two double-blind, randomized, placebo-controlled clinical trials involving 436 patients with multiple AKs. Patients were treated with Aldara or placebo cream twice per week for 16 weeks. At eight weeks post-treatment, half of the patients treated with Aldara had at least an 83 percent reduction in the number of AK lesions counted at baseline versus 0 percent in the placebo group. Complete clearance of AKs was seen in 45 percent of patients treated with Aldara versus 3 percent in the placebo group.

In these clinical studies, the most frequently reported adverse reactions were local skin and application site reactions, including flaking/scaling, induration, edema, erythema and scabbing/crusting.

Caused by cumulative sun exposure, AK lesions often appear as rough, red, scaly patches, crusts or sores on the top layer of skin. Left untreated, AK may progress to squamous cell carcinoma, the second-leading cause of skin cancer deaths in the United States. More than 80 percent of AK lesions occur on the upper limbs, head and neck. Because AKs can take years to develop, incidence increases as people age. Cases of AK have also been documented among younger people in their twenties and thirties, and are increasing as many continue to spend time outdoors and in the sun. In addition, recent data reported by the American Academy of Dermatology suggest that younger people may also be at risk for AK due to the increasing use of tanning beds by teens and younger adults.

3M Pharmaceuticals launched Aldara in 1997 for the treatment of external genital and perianal warts. Aldara is 3M's first IRM and works by stimulating the immune system to recognize and respond to virus infections and tumors in the skin. IRMs stimulate the body to produce specific cytokines, such as interferon-alpha, which are naturally occurring proteins used by cells of the immune system to communicate with each other. Cytokines induced by IRMs enhance cell-mediated immunity, a natural process by which the body controls or eliminates virus infected cells and tumor cells.

Aldara cream is the first and only patient-applied IRM and is available by prescription only. In the treatment of external genital and perianal warts, most local skin reactions were mild to moderate and included erythema, erosion, flaking, edema, scabbing and induration at the wart site. Most common application-site reactions were itching (26 percent), burning (16 percent) and pain (4 percent) at the wart site. Application-site pigmentation changes have also been reported.

New warts may develop during treatment. The effect of Aldara cream on the transmission of genital warts is unknown. Aldara cream may weaken condoms and diaphragms. Sexual contact should be avoided while the cream is on the skin.

Full prescribing information is available at www.3M.com/Aldara.

Forward-Looking Statements

This press release contains forward-looking statements about the potential of imiquimod for the treatment of actinic keratosis and superficial basal cell carcinoma that reflect the current beliefs of 3M. However, as with any pharmaceutical under development, there are substantial risks and uncertainties in the process of development and regulatory review. There are no guarantees that the product will receive regulatory approvals or prove to be commercially successful. For further discussion of these and other risks and uncertainties, see 3M's filings with the United States Securities and Exchange Commission. 3M undertakes no duty to update forward-looking statements.

About 3M

3M is a \$16 billion diversified technology company with leading positions in consumer and office; display and graphics; electronics and telecommunications; health care; industrial; safety, security and protection services; transportation and other businesses. Headquartered in St. Paul, Minnesota, the company has operations in more than 60 countries and serves customers in nearly 200 countries. 3M is one of the 30 stocks that make up the Dow Jones Industrial Average and also is a component of the Standard & Poor's 500 Index. For more information about 3M, go to www.3M.com/profile/pressbox/index.ihtml.

3M Health Care is one of seven major 3M businesses, serving medical, dental, pharmaceutical and personal care markets. 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.

Aldara is a trademark of 3M.

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