

3M Submits Supplemental New Drug Application to FDA for Aldara -imiquimod- Cream, 5% for the Treatment of Superficial Basal Cell Carcinoma

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

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3M announced today that the company has submitted a supplemental new drug application (sNDA) with the U.S. Food and Drug Administration to market Aldara (imiquimod) Cream, 5%, an immune response modifier (IRM), for the treatment of superficial basal cell carcinoma (sBCC), a common form of non-melanoma skin cancer. Approximately 1.3 million new cases of non-melanoma skin cancer occur in the United States each year. Of these, almost 1 million are basal cell carcinomas (BCCs). Aldara cream, currently the leading prescription treatment for external genital and perianal warts, is the first IRM application submitted for the sBCC indication. Additionally, 3M submitted a sNDA last month for Aldara cream for the treatment of actinic keratosis, a common precursor to skin cancer.

"This submission is a significant milestone in our efforts to bring Aldara cream to market for sBCC," said Barry Labinger, division vice president, Pharmaceuticals Division. "Aldara cream will represent an important new option for dermatologists and other physicians who are treating patients with this common form of non-melanoma skin cancer," he concluded. Labinger confirmed that 3M remains on track to receive an anticipated marketing approval in mid-2004 for this indication. 3M continues to build a pipeline for new IRM molecules for a broad range of indications.

The Aldara cream sNDA is based on positive results from two double-blind, randomized, placebo-controlled clinical trials involving 724 patients with sBCCs, confirmed by biopsy. Patients were treated with Aldara cream or placebo once daily, five or seven times per week, for six weeks. The clinical studies showed the optimal dosing to be five times per week, with a histological clearance rate of 82 percent in patients treated with Aldara cream compared to only 3 percent in the placebo group. Patients treated with Aldara cream seven times per week showed a histological clearance rate of 79 percent compared to 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, scabbing/crusting and ulceration. These reactions were generally mild to moderate ranging to severe in nature.

BCC is the most common form of non-melanoma cancer worldwide. In the vast majority of cases, it is thought to be caused by exposure to the harmful ultraviolet rays of the sun. According to the American Cancer Society, 35 percent to 50 percent of people diagnosed with one BCC will develop a new skin cancer within five years of the first diagnosis. Common treatments for BCC include excisional surgery, cryosurgery, MOHS micrographic surgery, curettage and electrodesiccation.

3M Pharmaceuticals launched Aldara cream in 1997 for the treatment of external genital and perianal warts. Aldara cream 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, clinical studies showed 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 for external genital and perianal warts. 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.

Forward-Looking Statements

This press release contains forward-looking statements about the potential of imiquimod for the treatment of actinic keratosis and sBCC 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.jhtml.

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

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