

Mochida Launches Beselna Cream 5% - First Therapeutic Agent for Condyloma Acuminatum in Japan

(Tokyo, November 26, 2007) - On December 10th, Mochida Pharmaceutical Co., Ltd. (Head Office: Shinjuku-ku, Tokyo, Japan; President: Naoyuki Mochida) will begin selling Beselna Cream 5% (imiquimod) as a therapeutic agent for condyloma acuminatum, commonly known as genital warts.

It is believed that imiquimod engages the patient's own anti-viral defense mechanisms to eliminate warts by stimulating cytokine (such as interferons) production, triggering antiproliferative activity against virus, and cytotoxic action against virus-infected cells by activating the cell-mediated immune response.

Outside of Japan, imiquimod is sold as Aldara™ and has been marketed in over 75 countries and regions since 1997, when it received US approval for use against condyloma acuminatum of the external genital and perianal areas. In 2001, Mochida in-licensed Aldara™ from US company 3M (current licensor is iNova Pharmaceuticals (Australia) Pty Limited, one of the regional buyers of 3M's pharmaceutical business) and has been developing the product for sale in Japan.

Condyloma acuminatum is a sexually transmitted infection caused by the human papilloma virus (HPV), and the disease produces anogenital lesions of a papular or horny appearance. Until now, no medication for this condition was available in Japan, and with macroscopic lesions typically removed using surgical therapies such as electrocauterization, carbon dioxide laser vaporization, liquid nitrogen cryotherapy or surgical excision, there was a need for rapid development of a usable medication.

Beselna Cream 5% is the first therapeutic agent for condyloma acuminatum in Japan, and by providing a new treatment option for this disease it is expected to contribute considerably to improving quality of life for patients.

For Reference

Brand Name: Beselna Cream 5%

Non-proprietary Name: Imiquimod

Indication: Condyloma Acuminatum (external genital or perianal only)

Ingredients and Contents: 12.5 mg imiquimod per sachet (250 mg)

Dosage and Administration: Beselna Cream 5% is applied at the optimum dose on the area of warts once a day for 3 times a week prior to normal sleeping hours. The Cream is left on the skin, and after getting up from sleep, the cream is washed off with mild soap and water (cold or warm).

NHI Drug Price Standard: 5% 250 mg sachet x 1 ¥1,136.00

Packet Contents: 12 sachets

Date of Approval for manufacturing and marketing: July 31, 2007

NHI Price Listing Date: September 21, 2007

Release Date: December 10, 2007

Manufacturer/Distributor: Mochida Pharmaceutical Co., Ltd.