



FOR IMMEDIATE RELEASE

FDA Approves Zyclara[®] (imiquimod) Cream, 3.75% for the Treatment of External Genital Warts

Zyclara Cream Offers a Short Daily-Dosing Cycle with Sustained Efficacy

BRISTOL, TN (March 25, 2011) – Graceway[®] Pharmaceuticals announced today that the Food and Drug Administration (FDA) has approved Zyclara[®] Cream for the treatment of external genital and perianal warts (EGW) in patients 12 years of age and older. Zyclara Cream’s clinical studies demonstrated that using its once-daily treatment regimen, for up to eight weeks, safely and effectively clears genital warts. In addition, data showed that of those patients who achieved complete clearance, only a small number experienced a recurrence of their wart(s) 12 weeks after treatment.

Most approved topical prescription treatments currently available to treat EGW are associated with lengthy treatment regimens, which may impact patient compliance. Zyclara Cream was developed to meet the need for a shorter treatment regimen, while maintaining the efficacy (both initial and sustained clearance) that imiquimod has delivered for more than a decade.

Two Phase III double-blind, placebo-controlled efficacy and safety studies of imiquimod 3.75% cream evaluated complete clearance of all warts - defined as clearance of baseline and emergent warts - across several anatomical locations. In an intent-to-treat analysis of all participants who began the study, regardless of whether they completed it, complete clearance of all warts was achieved in 28.3 percent of patients on imiquimod 3.75% cream, compared to 9.4 percent on placebo cream. Additionally, efficacy was greater in females than males for all primary and secondary efficacy measurements, and 37 percent of females on the 3.75% formulation achieved complete clearance compared to 19 percent of males.

In subjects with complete clearance only 15 percent treated with imiquimod 3.75% cream experienced a recurrence of their warts within 12 weeks.

“Genital warts are caused by the human papillomavirus. Zyclara Cream, which represents a significant advancement in the topical treatment of genital warts, works by increasing the immune response,” said Anita Nelson, M.D., Department of Obstetrics and Gynecology, Harbor UCLA Medical Center, Los Angeles. “In my professional experience, genital warts commonly recur after treatment. Zyclara Cream showed promising results in preventing genital wart recurrence for twelve weeks in the majority of patients who cleared during the clinical study.”

The most frequently reported adverse events were local skin and application site reactions. Overall, less than 1 percent of subjects treated with Zyclara Cream discontinued due to local skin / application site reactions. Local skin reactions included redness, swelling, sores or blisters, and draining (weeping).

“Many of the currently approved topical treatments for genital warts are not ideal due to lengthy and confusing dosing regimens,” said Jefferson J. Gregory, chairman and CEO of Graceway Pharmaceuticals. “Our vision for Zyclara Cream is to improve the patient experience by offering a more intuitive dosing regimen (once daily treatment for up to eight weeks) with the goal of improving patient compliance.”

About EGW

EGW are caused by human papillomavirus (HPV), a sexually transmitted disease passed through genital contact. Overall, 5.6 percent of 18-to 59-year olds in the U.S. reported that they had ever been diagnosed with EGW, according to the National Health and Nutrition Examination Survey data collected from 1999 - 2004.

Warts usually appear as a small bump or groups of bumps in the genital area and can be small or large, raised or flat, or shaped like a cauliflower. Warts can appear within weeks or months after sexual contact with an infected partner - even if the infected partner has no signs of genital warts.

The treatment goal for EGW is the eradication of visible disease rather than the elimination of the HPV infection.

About Zyclara[®] (imiquimod) Cream, 3.75%

Zyclara Cream is a skin-use only (topical) prescription medicine used to treat external genital and perianal warts in people 12 years and older. Do not get Zyclara Cream in or on your anus or vagina.

When using Zyclara Cream, the most common side effects involve skin reactions in the application area. These include redness, swelling, sores or blisters, and draining (weeping).

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

For more information on Zyclara Cream, visit www.ZyclaraCream.com.

About Graceway® Pharmaceuticals, LLC

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