Daily Imiquimod Bests Placebo for Genital Warts

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FROM THE ANNUAL MEETING OF THE INFECTIOUS DISEASES SOCIETY FOR OBSTETRICS AND GYNECOLOGY

SANTA FE, N.M. – Imiquimod 2.5% and 3.75% creams applied daily for up to 8 weeks were both well tolerated and more efficacious, compared with placebo, in treating external genital warts in women, results from two combined randomized studies showed.

In particular, the 3.75% formulation “fulfills a need for a shorter and simpler imiquimod treatment for external genital warts and provides a clinically meaningful benefit with respect to complete clearance of all baseline and new warts and a rapid reduction in wart counts, with an acceptable safety profile,” Dr. David A. Baker said at the meeting.

Imiquimod 5% cream is approved to treat external genital warts and actinic keratoses. This formulation has been shown to be safe and effective, but Dr. Baker noted that the efficacy end points “were based on the analysis of baseline target warts only, and the compliance with three times per week dosing frequency up to 16-week treatment duration may be difficult for some patients to follow.”

In two identical phase III studies, Dr. Baker and his associates randomized 534 women to placebo, imiquimod 2.5% cream, or imiquimod 3.75% cream for the treatment of genital warts. Graceway Pharmaceuticals, which manufactures imiquimod, developed the formulations “to allow daily dosing to treat external genital warts as well as actinic keratoses,” said Dr. Baker, professor of obstetrics, gynecology, and reproductive medicine at Stony Brook (N.Y.) University.

The 3.75% imiquimod cream has Food and Drug Administration approval to treat actinic keratoses. Graceway is waiting FDA approval of the 3.75% cream to treat external genital warts, Dr. Baker said in a later interview.

The mean age of study participants was 33 years, the mean duration of disease was 5.6 years, the mean wart count was 7.9, and the mean total wart area was 166.3 mm². Up to 250 mg of cream per dose was applied once daily to warts for up to 8 weeks or until complete clearance. At 12 weeks, sustained complete clearance was assessed in women who had initial complete clearance.

In the intent to treat analysis, Dr. Baker reported that initial complete clearance of all external genital warts was achieved in 14% of the placebo group, 28% of the imiquimod 2.5% group, and 37% of the imiquimod 3.75% group. Per-protocol results were similar (16%, 35%, and 43%, respectively).

Of the women who achieved initial complete clearance and entered the 12-week follow-up, complete clearance was sustained in 100% of the placebo group, 60% of the imiquimod 2.5% group, and 65% of the imiquimod 3.75% group.

In terms of safety, 0.9% of women in the placebo group, 1% of women in the imiquimod 2.5% group, and 2% of the women imiquimod 3.75% group discontinued the study early due to safety-related reasons.

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