

# Daily Imiquimod Bests Placebo for Genital Warts

BY DOUG BRUNK

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



**The 3.75% formulation ‘fulfills a need for a shorter and simpler imiquimod treatment.’**

DR. BAKER

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 mm<sup>2</sup>. 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. ■

## VITALS

**Major Finding:** Investigative formulations of 2.5% and 3.75% imiquimod cream applied daily for up to 8 weeks for the treatment of external genital warts in women yielded complete clearance rates of 28% and 37%, respectively, compared with 14% in women using placebo cream.

**Data Source:** Two combined phase III studies of 534 women who were treated at 37 sites in the United States.

**Disclosures:** Dr. Baker disclosed that he is a research consultant for Graceway Pharmaceuticals.

For patients with type 2 diabetes whose blood glucose is uncontrolled with orals alone

ADVERTISEMENT

# THE ROAD TO BLOOD GLUCOSE CONTROL MAY START HERE...

## INSULIN

IMPROVING BLOOD GLUCOSE CONTROL SHOULDN'T WAIT

### Indications and Usage for Lantus<sup>®</sup> (insulin glargine [rDNA origin] injection)

Lantus<sup>®</sup> is a long-acting insulin analog indicated to improve glycemic control in adults and children (6 years and older) with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. Lantus<sup>®</sup> should be administered once a day at the same time every day.

**Important Limitations of Use:** Lantus<sup>®</sup> is not recommended for the treatment of diabetic ketoacidosis. Use intravenous short-acting insulin instead.

Lantus<sup>®</sup> SoloSTAR<sup>®</sup> is a disposable prefilled insulin pen.

### Important Safety Information for Lantus<sup>®</sup>

#### Contraindications

Lantus<sup>®</sup> is contraindicated in patients hypersensitive to insulin glargine or one of its excipients.

#### Warnings and Precautions

Monitor blood glucose in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision. Changes in insulin strength, manufacturer, type, or method of administration may result in the need for a change in insulin dose or an adjustment in concomitant oral antidiabetic treatment.

**Please see additional Important Safety Information for Lantus<sup>®</sup> continued on the next page.**

From the maker of  
LANTUS<sup>®</sup> SoloSTAR<sup>®</sup>

