**HSV-1 Likely Cause of New Genital Infections**

**BY ELIZABETH MECHCATIE Senior Writer**

**CHARLESTON, S.C.** — Once-daily treatment with valacyclovir for the suppression of genital herpes caused by herpes simplex virus type 2 was well tolerated for up to 20 months in a recent study.

Previously, data were available only for patients who used daily valacyclovir for up to 12 months. Zane A. Brown, M.D., of the University of Washington, Seattle, and his colleagues reported in a poster at the annual meeting of the Infectious Diseases Society for Obstetrics and Gynecology for Obstetrics and Gynecology.

For the current study, which was supported by GlaxoSmithKline Inc., 1,484 serodiscordant, heterosexual, monogamous couples were enrolled, and the seropositive partner was randomized to receive either placebo or 500 mg/day of valacyclovir for 8 months. The results of this double-blind phase, which were previously reported by the investigators, showed that the treatment significantly reduced the risk of genital herpes transmission.

Following the double-blind phase, 1,018 of the 1,484 participants treated in the double-blind phase entered an open-label suppression phase of the study, which provided 12 months of suppressive therapy with 500 mg/day of valacyclovir. Patients in this phase were evaluated every 3 months for laboratory values and adverse events.

More than 85% of participants who completed the entire 20 months of treatment were at least 80% compliant with the study medication. During the double-blind and open-label phases, the nature and incidence of adverse events were similar in the 519 participants originally assigned to receive valacyclovir (treatment group) and the 499 originally assigned to receive placebo. Common adverse events included headache, nasopharyngitis, and upper respiratory tract infection.

Serious adverse events were reported infrequently and were similar in frequency in the treatment group (5% incidence rate) and the placebo group (5% incidence rate). Only one serious adverse event (gastroenteritis in one patient) during the 20-month study was considered by the investigators to be possibly attributable to valacyclovir, and it occurred during the open-label portion of the study.

Adverse events leading to treatment discontinuation occurred in fewer than 1% of those in the treatment group, and in 1% of those in the placebo group; clinically significant laboratory abnormalities occurred in 6% of patients in both groups. No deaths occurred during the study period.

Despite prior lack of data on the safety of valacyclovir for the suppression of genital herpes when used for longer than 12 months, some physicians prescribe this therapy for patients older than 18 months. The investigators noted that these findings suggest that the treatment is as safe for up to 20 months as it is with 8-12 months of suppressive therapy, they concluded.

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**Valacyclovir Safe for Long-Term Suppression of Genital Herpes**

**By Sharon Worcester Southeast Bureau**

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**HPV Testing May Help in Managing Cervical Lesions**

**By Sherry Boschert San Francisco Bureau**

**VANCOUVER, B.C.** — Low-grade squamous intraepithelial lesions were likely to regress in women older than 30 years who were not infected with types of human papillomavirus associated with a high risk for cervical cancer, a longitudinal study found.

Of 412 women with untreated cervical low-grade squamous intraepithelial lesions (L-SIL), only women who tested positive for high-risk human papillomavirus (HPV) developed cervical intraepithelial neoplasia grades 2 or 3 (CIN 2/3) during 2 years of follow-up, Christine C. Clavel, Ph.D., said at the 22nd International Papillomavirus Conference.

HPV testing is approved in the United States to triage women with Pap results showing atypical squamous cells of undetermined significance, or as an adjunct to Pap smears for screening women older than age 30. The study suggests that it also might be helpful by allowing a longer interval between follow-up in women with L-SIL and a negative HPV test, said Dr. Clavel of the University of Reims (France) Hospital Center.

At baseline, 87% of the 412 women and 80% of those older than 35 years tested positive for high-risk HPV types. Colposcopy and biopsies found 21 cases of CIN 2/3 at base- line and an additional 12 cases during the 2-year follow-up, all in women who initially tested positive for high-risk HPV, she said at the conference, sponsored by the University of California, San Francisco.

Half of the high-risk HPV infections cleared over a median of 9 months in the cohort as a whole and in the subset of women older than 35 years. Cytologic lesions cleared over time in 66% of the total cohort and in 68% of women older than 35.

“There was a significant correlation observed between an initial negative high-risk HPV test, the regression of cytologic lesions, and the absence of CIN 2/3 in follow-up,” Dr. Clavel said.

Women with L-SIL who test negative for high-risk HPV might safely be followed 12 months later by repeat cytology and HPV testing, she said. This would include approximately 13% of all women with L-SIL, 20% of these over age 35 with L-SIL, or 24% of women over age 45 with L-SIL. In women older than 45 years, misclassification of L-SIL increases and leads to a decrease in detection of L-SIL at colposcopy, she noted.

Using HPV testing plus Pap smears to follow HPV-negative women with L-SIL could significantly decrease the number of women sent to colposcopy, compared with follow-up using cytology alone, Dr. Clavel said.

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**Infectious Diseases**

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