New Agent Effective in Preventing Cold Sores

BY DOUG BRUNK

SAN FRANCISCO — A newly approved cream containing 5% acyclovir and 1% hydrocortisone prevented ulcerated lesions in patients with recurrent herpes simplex labialis, compared with both topical acyclovir and placebo, a large multicenter study showed.

The product, ME-609 (brand name not yet determined), is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten lesion healing time.

"This is the first product to prevent the development of cold sores," Dr. Spotswood L. Spruance said in an interview during a poster session at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy. "Other products have been shown to reduce the duration of the disease, but this has been shown to block the development of ulcers and blisters."

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DR. SPRUANCE

ME-609 is not yet available in the United States because Medivir, the Swedish company that developed the agent, has not yet partnered with a company to distribute and market it. ME-609 should be available in the United States this year.

For the study, researchers led by Dr. Christopher M. Hull of the department of dermatology at the University of Utah, Salt Lake City, randomized 1,443 patients aged 18 years and older with at least three episodes of herpes simplex labialis to one of three treatment groups: ME-609 vehicle containing 5% acyclovir and 1% hydrocortisone (601 patients), acyclovir alone in ME-609 vehicle (610), or placebo (232). The patients were instructed to start treatment at home five times daily for 5 days at the earliest sign or symptom of their next recurrence of herpes simplex labialis, and to keep a diary of symptoms.

The mean age of patients was 44 years, and 28% were male.

The researchers collected safety and efficacy data from patient diaries and from daily clinical visits. The primary study end point was prevention of ulcerative lesions, defined as abortive episodes that did not progress beyond the papule stage.

Secondary end points included episode duration to loss of hard crust, lesion healing time to normal skin, maximum lesion area, and cumulative lesion area.

Dr. Spruance, of the division of infectious diseases at the University of Utah, reported that at the end of treatment, the proportion of patients with nonulcerative recurrences was 42% in the ME-609 group, compared with 35% for acyclovir and 26% for placebo.

Among patients who developed an ulcerative lesion despite treatment, the duration of lesions was reduced by ME-609 to a similar extent as acyclovir alone (5.7 days vs. 5.9 days, respectively); both were significantly shorter than placebo (6.5 days), he said at the meeting, which was sponsored by the American Society for Microbiology.

Lesion healing time was reduced by ME-609 to a similar extent as acyclovir alone (9.6 days vs. 9.9 days, respectively), with both significantly shorter than placebo (11 days).

Maximum lesion area was smallest in the ME-609 group, Dr. Spruance reported, but the differences compared with the other groups did not reach statistical significance. The cumulative lesion area, however, was reduced by half in the ME-609 group, compared with the placebo group, and the differences in cumulative lesion area between ME-609 and the other two groups were statistically significant. The frequency and nature of adverse events was similar between the groups. ■

Disclosures: *Medivir funded the study. Dr. Spruance disclosed that he is a paid consultant for the company.*