New Cream May Prevent Cold Sore Recurrence

BY DOUG BRUNK
SAN FRANCISCO — A newly approved cream containing 5% acyclovir and 1% hydrocortisone prevented ulcerated lesions in patients with recurrent herpetic lesions. The cream was significantly more effective than placebo and was associated with a reduced likelihood of ulcerative cold sores and a shorter lesion healing time.

“This is the first product to prevent the development of cold sores,” Dr. Sprouse said in an interview. “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.”

Developed by Medivir of Huddinge, Sweden, ME-609 is not yet available in the United States because Medivir has not yet partnered with a company to distribute and market the product. A company spokeswoman estimated that ME-609 would be available in the United States some time in 2010.

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 herpetic lesions to one of three treatment groups: ME-609 vehicle containing 5% acyclovir and 1% hydrocortisone (n=601), acyclovir alone in ME-609 vehicle (n=610), or placebo (n=232).

The patients were instructed to start treatment at home five times daily for 5 days. At the end of the study, patients who had received ME-609 had a significantly shorter median duration of disease compared with the placebo group. The mean duration of disease was 9.9 days in the placebo group compared with 9.6 days in the ME-609 group, a difference of 0.3 days.

The cumulative lesion area was significantly lower in the ME-609 group compared with the placebo group. The mean cumulative lesion area was 1.9 cm² in the placebo group compared with 1.3 cm² in the ME-609 group, a difference of 0.6 cm².

The patients whose lesions were microbiologically evaluable, 96% achieved a clinical cure, including 95.7% of the patients with methicillin-susceptible S. aureus infections and 96.9% of the patients with methicillin-resistant S. aureus infections.

Investigational Antibiotic for MRSA Found Effective, Safe

BY ROBERT FINN
SAN FRANCISCO — A short course of therapy with torezolid phosphate cured virtually all patients with Staphylococcus aureus–based severe complicated skin and skin structure infections in a randomized, double-blind, phase II study. A second-generation oxazolidinone related to linezolid, torezolid phosphate is a produg that can be given orally once per day. Dr. Philippe Prokocimer said in an interview. Dr. Prokocimer is medical director of Titus Therapeutics, the San Diego–based company that is developing the drug. He was one of the authors of the study, which was presented in a poster at the Interscience Conference on Antimicrobial Agents and Chemotherapy, sponsored by the American Society for Microbiology.

The study involved 192 patients with S. aureus infections who were randomized to receive 200 mg, 300 mg, or 400 mg of torezolid phosphate once a day for 5–7 days. All patients had severe complicated skin and skin structure infections (cSSSI, also called acute bacterial skin structure infections), defined as skin infections that were 5 cm or greater in diameter and/or included systemic signs of infection. Patients with uncomplicated disease or with infections requiring gram-negative coverage were excluded, as were immunocompromised patients and those who had used antibiotics for more than 24 hours within 96 hours after the start of therapy. The clinical outcomes were similar in all dosage groups. Of the patients whose lesions were microbiologically evaluable, 96% achieved a clinical cure, including 95.7% of the patients with methicillin-susceptible S. aureus infections and 96.9% of the patients with methicillin-resistant S. aureus infections.

Five of the patients in the study experienced serious adverse events, but only one of these could have been drug related—a case of acute cholecystitis in an obese 57-year-old woman 2 days after the end of therapy. All other treatment-emergent adverse events were mild or moderate, with nausea the most common (19% of patients).

The investigators saw no clinically significant changes in QTc.

“The side effect profile is stellar,” Dr. Prokocimer said. “When we increase the dose, we don’t see a dose-related increase in the incidence of side effects.”

He noted that unlike linezolid, the 200-mg dose of torezolid phosphate had virtually no effects on patients’ laboratory values. “We start to see effects of immunosuppression. The 200-mg dose will be the subject of two pivotal phase III studies, due to begin in 2010.”

FDA Approves Gardasil for Boys and Cervarix for Girls

BY LORI BUCKNER FARMER
The Food and Drug Administration has approved the drug Gardasil for boys and men aged 9–26 years and Cervarix for girls and women aged 10–25 years.

Gardasil was approved for preventing genital warts associated with the human papillomavirus (HPV), according to a statement from the drug’s manufacturer, Merck & Co. An FDA press officer confirmed the approval.

HPV vaccine offers protection against four strains of the virus (types 6, 11, 16, and 18) that have been associated with the most disease, including cervical cancer in women (types 16 and 18) and genital warts in both women and men (types 6 and 11), according to the statement.

Gardasil is not recommended for pregnant women or for individuals with hypersensitivity (including severe allergy) to yeast, according to the drug’s safety information.

HPV vaccination in males "may be more relevant to dermatologists," said Dr. Stephen K. Tyring, clinical professor of dermatology at the University of Texas Health Science Center in Houston. “We don’t get a lot of women asking about the HPV vaccine, but we may see more men.” Pe-diatrians and gynecologists typically counsel and vaccinate girls and women against HPV.

This is “big news in the world of papillomavirus,” Dr. Tyring said at the women’s and pediatric dermatology seminar sponsored by Skin Disease Education Foundation (SDEF). Dr. Tyring is a consultant, has received grant/research support, and is on the speakers’ bureau for Merck and GlaxoSmithKline. SDEF and this news organization are owned by Elsevier.

Cervarix, a recombinant bivalent HPV vaccine was also approved by the FDA for the prevention of cervical cancer and certain precancerous or dysplastic lesions caused by HPV types 16 and 18 in girls and women.

The FDA followed the advice of its Vaccines and Related Biological Products Advisory Committee, which found that data supported the efficacy of the vaccine for preventing HPV 16/18-related cervical cancer, cervical intraepithelial neoplasia (CIN) 2+, and adenocarcinoma in situ (AIS) in girls and women aged 13–25 years.

The vaccine, which will be marketed by GlaxoSmithKline Biologicals as Cervarix, is administered in a three-dose schedule at 0, 1, and 6 months.

The advisory panel also had found that an immunogenicity bridging study from the United Kingdom—which compared immune responses to the vaccine in recipients aged 10–14 years with those of older recipients—supported effectiveness of this same claim in girls aged 10–14 years.

There were no efficacy data in the younger age group, but immune responses for HPV 16/18 in the younger girls were similar to those in the older group.

The majority of the panel also voted that the data supported the safety of the vaccine in girls and women aged 10–25 years but recommended that safety issues, which included spontaneous abortions, be studied further after licensure.

In the pivotal study, there were a higher number of spontaneous abortions around the time of vaccination than in the comparison group.

The company has also announced plans to conduct a postmarketing safety study.

There were more musculoskeletal and neuroinflammatory events with potential autoimmune causes—although rare—at least 6,200 Cervarix recipients, compared with controls. The three most common adverse events associated with the vaccine were headache, injection site pain, and fever.

Heidi Splete and Damian McNamara contributed to this report.