Nanoemulsion Speeds Herpes Labialis Healing

BY MICHAEL KAUFMAN

SAN FRANCISCO — NB-001, a novel topical antiviral nanoemulsion, significantly improved time to healing of herpes labialis by more than 1 day, judging from the findings of a randomized, double-blind, vehicle-controlled trial of more than 900 people.

"The improvement in time to healing [defined as the difference in hours between first treatment and healing, divided by 24 hr/day] was similar to that reported for oral nucleoside analogues," reported Dr. Terry Jones, a dermatologist who is an investigator with J and S Studies Inc. of Bryan, Tex., which conducted the study for NanoBio Corp., the developer of NB-001.

Although oral nucleoside analogues—including ganciclovir, acyclovir, and famciclovir—have been shown to be effective, they are infrequently prescribed because of concerns over the potential development of drug resistance, said Dr. Jones at the annual meeting of the American Academy of Dermatology.

Dr. Jones and his associates assessed the clinical efficacy of three concentrations of NB-001, which is designed to permeate to the site of infection and kill virus by fusing with the viral envelope, causing disruption and viral lysis.

The novel mechanism of action renders the emergence of drug resistance "highly unlikely," said Dr. Jones, who also is in private practice in College Station, Tex. The size of the nanoemulsion droplets (180 nm) prevents them from entering the tight junctions of epithelial cells, minimizing the potential for irritation or systemic absorption, he noted.

The 919 subjects enrolled in the study were 18-80 years old and had a history of three cold-sore outbreaks per year. They were randomized to receive one of four treatments (NB-001 0.1%, 0.3%, or 0.5%, or vehicle) and were instructed to apply 200 mcL five times daily at the first sign of recurrence for up to 4 days. The subjects returned to the clinic within 12 hours of the onset of symptoms, and daily thereafter, for assessments of lesion stage. Lesions were considered to be healed when the skin had returned to normal and no scabs remained.

Of the 919 subjects, 482 had a recurrence and started treatment. "All treatments were well tolerated with no safety concerns or systemic absorption," Dr. Jones said. Of the three active regimens, the 0.3% formulation provided the highest tissue levels of NB-001 and resulted in a significant improvement in time to healing (1.3 days, compared with vehicle).

A subset analysis of subjects considered by the investigator to be at the prodromal or erythematic stage at baseline indicated a time to healing of 3.6 days for subjects who were treated with 0.3% NB-001. This, said Dr. Jones, was nearly 2 days improvement over vehicle.

"In subjects with no lesion at baseline, NB-001 provides a significant clinical advantage over current topical and systemic agents," he said.

The same patients were included in the safety population for an evaluation of the safety, tolerability, and pharmacokinetics of topical NB-001, results of which were reported by Dr. Michael Jarratt, an investigator for DermResearch Inc. in Austin, Tex., which conducted the study. A subset of subjects had pharmacokinetic sampling following application of medication to an open lesion. The samples were analyzed for circulating levels of cetylpyridinium chloride (CPC), a marker for the nanoemulsion.

The study subjects experienced few adverse events, and those observed were generally mild to moderate "as expected for the population," said Dr. Jarratt, who also presented the data at the annual meeting of the AAD. One subject experienced "facial burning" at the application site, but that was considered to be unrelated to the study medication. Two subjects discontinued early because of adverse events that were also considered to be unrelated to NB-001.

Investigators found no detectable CPC in 99% of the plasma samples. Four samples had minimally detectable levels; two of those were obtained from subjects who had been randomized to the vehicle.

Both Dr. Jones and Dr. Jarratt reported receiving research support from NanoBio Inc. ■