A Pilot Study to Evaluate the Safety and Efficacy of NVC-422 Topical Gel in Impetigo, Including MRSA

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**Abstract**

Background: Impetigo is a highly contagious superficial bacterial infection of the skin that affects mostly children. Most cases are caused by Staphylococcus aureus, Streptococcus pyogenes, or a mixture of both bacteria. Methicillin-resistant S. aureus (MRSA) is an important cause of community and hospital-acquired infections. Staphylococcal and streptococcal beta-lactamase activity against various, yeasts, fungi, and bacteria. NVC-422 was delivered in a gel formulation that was used to evaluate safety and efficacy in clinical studies.

**Methods**

Children aged 2-12 years with primary impetigo were randomized after written informed consent was obtained from the parent or guardian. The study group included 2 different treatments in an effort to determine the therapeutic dose for further study, a low, medium, and high dose.

Sixty subjects were randomized in 2 equal groups in the study (3 days for 7 days to all randomized subjects. Response was measured by the Skin Infection Rating Scale (SIRS) and microbiological eradication.

**Results**

A total of 120 patients were randomized. Clinical and microbiological success was seen in 94% - 97% of all evaluable subjects after completion of treatment; the majority of the infections were S. aureus, with approximately 10% of those being MRSA, which responded at the same rate as non-MRSA infections. About 13% of the infections were mixed infections or S. pyogenes alone. Approximately 5% of subjects had a treatment emergent adverse event with a possible causal relationship to treatment. Conclusion: Based on the results of this study, NVC-422 is a potentially useful novel, non-antibiotic, anti-microbial drug for the treatment of impetigo and further studies are warranted.

**Discussion and Conclusion**

- Overall clinical response rate (success and improvement) in the PPC population was equal to or above 80% in all of the dose groups at EOT (85%, 79% and 92% in the 0.1%, 0.5% and 1.5% dose groups respectively). This response rate is substantially higher than the response rate anticipated for placebo (30-50%). Similar responses were seen in the MITT population (83%, 84% and 93% in the 0.1%, 0.5% and 1.5% dose groups respectively).
- Response rates for MRSA infections were 100% (10/10) across all treatment groups in the PPC population, whether MRSA was the sole organism or in a mixed infection.
- All subjects that were Clinical Responders at Day 8 that returned for the follow-up visit at Day 15 were clinical successes with a SIRS score of less than or equal to 0 and no clinical signs of infection.
- There were no recurrences of infection at the follow-up visit (Day 15) in any treatment groups.
- Clinical and bacteriological response rates across the treatment groups support a dose-response, although differences were not statistically significant.
- Adverse events (7/121, 5.4%) were mild to moderate in severity and predominately were local reactions at the application site. All adverse events resolved after the end of treatment.
- The rate for subject treatment completion was 96% and 82% of the patients were treatment completers at the Day 15 visit.
- This proof-of-concept study demonstrates the activity of NVC-422 topical gel in the treatment of impetigo.