LTX-109 - A Novel Antimicrobial Drug in the Treatment of Impetigo

D. BLANCO, J. FERNÁNDEZ, H. WOLD, A. FUGELI, F. BJERKELY, B. MORTENSEN, M. HUSBYN, W.M. OLSEN

Instituto Dermatológico and Hospital Infantil Dr. Reid Cabral, Dominican Republic, Lytix Biopharma, Oslo, Norway

Introduction

LTX-109 is a novel antimicrobial drug constituted of a 14-mer peptide bearing an N-terminal tripeptide having a rapid lysing mode of action. Its rapid effect is mainly caused by a dual mechanism of action, including an antibacterial action against resistant bacterial strains such as MRSA. The present study was designed to investigate the efficacy and safety of two dose levels of LTX-109 in patients with impetigo.

Methods

Baseline evaluations

- Patients with a history of impetigo
- Baseline (Day 1) S. aureus (1% and 2%) given 3 times daily (TID) for 5 days in patients with impetigo.

Patient selection

- Positive Csw+ cultures
- Target lesion < 2 cm²
- Total SIRS-4, 1 and 3 for exudate and pus

Primary endpoint

- Bacteriological response defined as:
  - Resolution of signs and symptoms of infection of the target lesion.
  - Clinical improvement defined as:
    - Clinical success: The causative pathogen isolated from the target lesion at baseline (Day 1) (success: the causative pathogen isolated from the target lesion at baseline (Day 1) was eradicated).
  - Clinical failure defined as:
    - Clinical success: The causative pathogen isolated from the target lesion at baseline (Day 1) was still present at study completion.

Results

LTX-109 1% showed an eradication rate of 52% (clinical success) and 9% (clinical failure) in the MITT population compared to 22% (clinical success) and 16% (clinical failure) in the placebo group. The 2% dose showed an eradication rate of 41% (clinical success) and 7% (clinical failure) in the MITT population compared to 24% (clinical success) and 18% (clinical failure) in the placebo group.

Discussion

- The study results show that clinical effect is associated with bacteriological response, i.e. bacterial eradication by LTX-109 correlated with clinical success.
- Both doses of LTX-109 were found to be well-tolerated when applied to impetigo lesions.
- The study population of 206 patients is a total of 104 LTX-109 were reported and only one considered as possibly related to the study drug LTX-109 kills bacteria, regardless of resistance, has a different mechanism of action than existing antibiotics. Due to the increasing incidence of resistant bacteria there is an urgent need for new and effective alternatives for topical treatment of skin infections.

Conclusions

- Treatment of impetigo with LTX-109 was safe and well tolerated.
- The clinical success rate of LTX-109 was higher than placebo in both treatment groups at visit 3 and 4, demonstrating a dose response relationship.
- The bacteriological response was higher in the 2% LTX-109 group than in the placebo group.

References

10. Pathways to the development of LTX-109 in the follow-up period (n = 101) were as follows: Clinical success: 79 (79%), Clinical failure: 14 (14%), Clinical improvement: 5 (5%), Clinical failure: 19 (19%).

Lytix Biopharma AS | Fossumveien 71 | NO-3534 Trondheim, Norway | E-mail: postmaster@lytixbiopharma.com | Phone: +47 77 57 55 01 | Fax: +47 77 57 55 01

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