Omiganan demonstrates pharmacodynamic and clinical activity in patients with mild to moderate atopic dermatitis

T. Buters[1], T. van der Kolk[1], H. van der Wall[1], G.K. Hogendoorn[1], R. Rijneveld[1], S. van Luijten[1], D. van Alewijk[4], E. van den Munckhof,[4] M.L. de Kam,[1] G. Feiss[2], E.P.Prens[3], J. Burggraaf[1], M.B.A. van Doorn[3], R. Rissmann[1]

[1]Centre for Human Drug Research, Leiden, the Netherlands, [2]Cutanea Life Science, Wayne, Pennsylvania, USA , [3]Department of Dermatology Erasmus Medical Centre, Rotterdam, the Netherlands , [4] DDL Diagnostic Laboratory, Rijswijk, The Netherlands

Introduction

Omiganan is an indolicidin analogue with antimicrobial and immunomodulatory properties due to which omiganan could be beneficial to patients with atopic dermatitis (AD).

Aim

To explore efficacy and pharmacodynamics of omiganan in patients with mild to moderate AD.

Methods

- Randomized, double-blind, placebo-controlled, single-center phase IIa study
- 36 patients with mild to moderate AD
- At least one antecubital fossa (target lesion) affected
- 1:1:1 omiganan 1%, omiganan 2.5% or placebo
- Target lesion application QD for 28 days
- Mobile app for treatment compliance
- Efficacy: local oSCORAD, %BSA, pruritus
- Pharmacodynamics: skin microbiome swabs and biopsies

Results

- Significant reduction ($p<0.05$) oSCORAD of the target lesion (figure 1)
- Significant reduction ($p<0.05$) morning itch of the target lesion (figure 2)
- Trend in reduction %BSA target lesion
- Shift from lesional to non-lesional skin microbiome profile (figure 3)
- Reduction in *Staphylococcus* abundance
- Increase in diversity
- No safety issues

Conclusions

- Pharmacological activity of omiganan in patients with mild to moderate AD in the oSCORAD and pruritus
- Future studies needed to explore the full potential

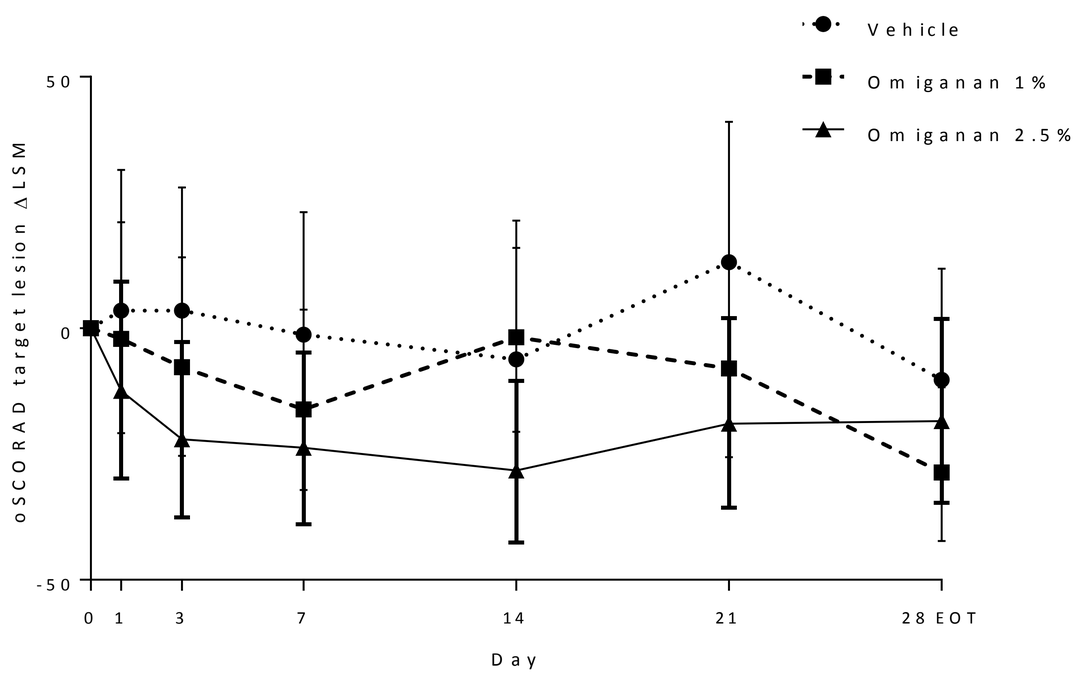

Figure 1: Local oSCORAD of the target lesion from pre-dose to end-of-treatment

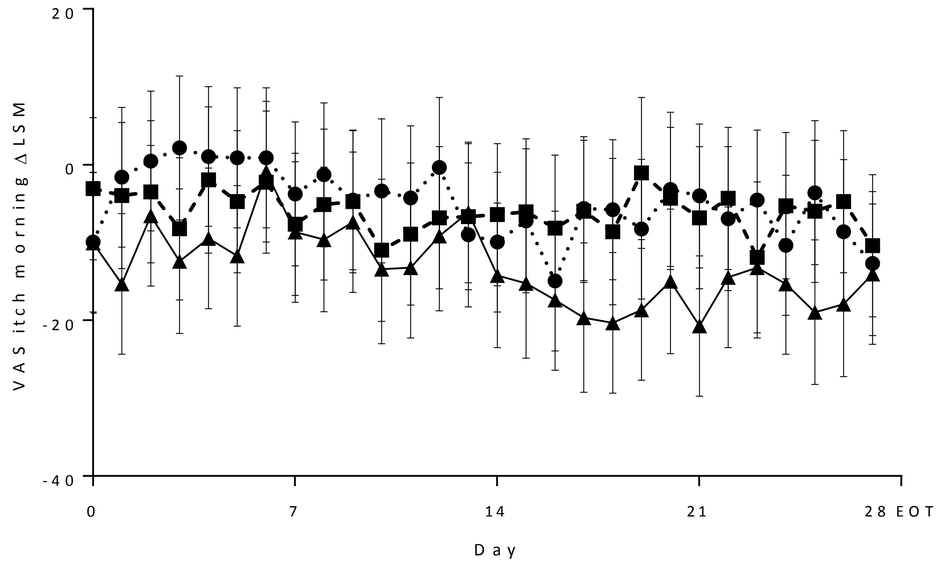

Figure 2: VAS morning itch of the target lesion from pre-dose to end-of-treatment

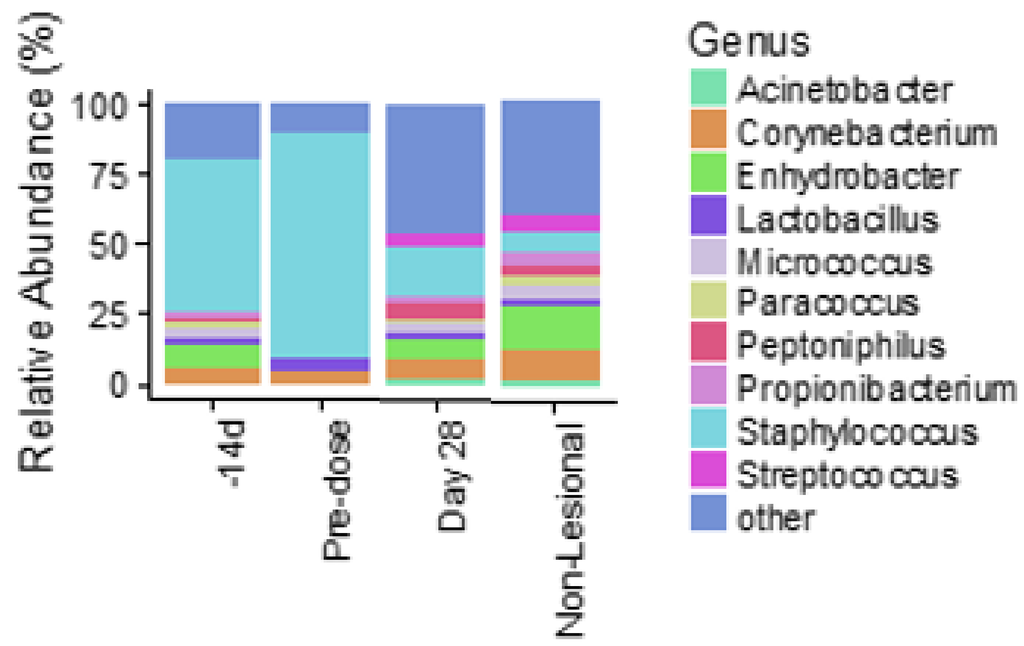

Figure 3: Example of microbiome profile of omiganan 2.5% treated patient. A shift from lesional to non-lesional profile is observed from pre-dose to end-of-treatment

CHDR
Centre for Human Drug Research

Centre for Human Drug Research | Zernikedreef 8 | 2333 CL Leiden | The Netherlands | Tel +31 71 52 46 400 | info@chdr.nl | www.chdr.nl