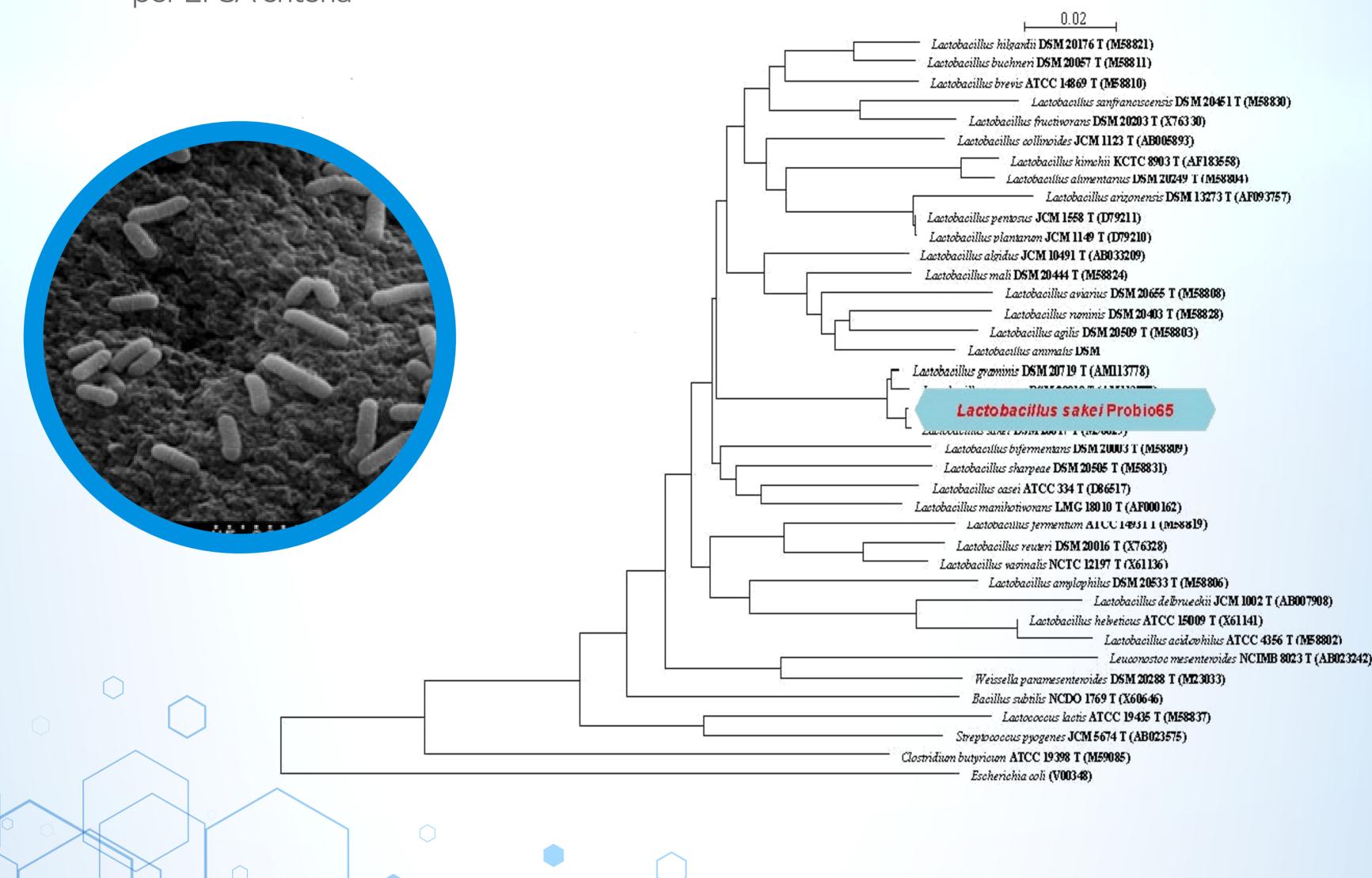
- Lack of antibiotic resistance*
- * per EFSA criteria



affects the skin Gut microbiota can induce regulatory T_{REG} and

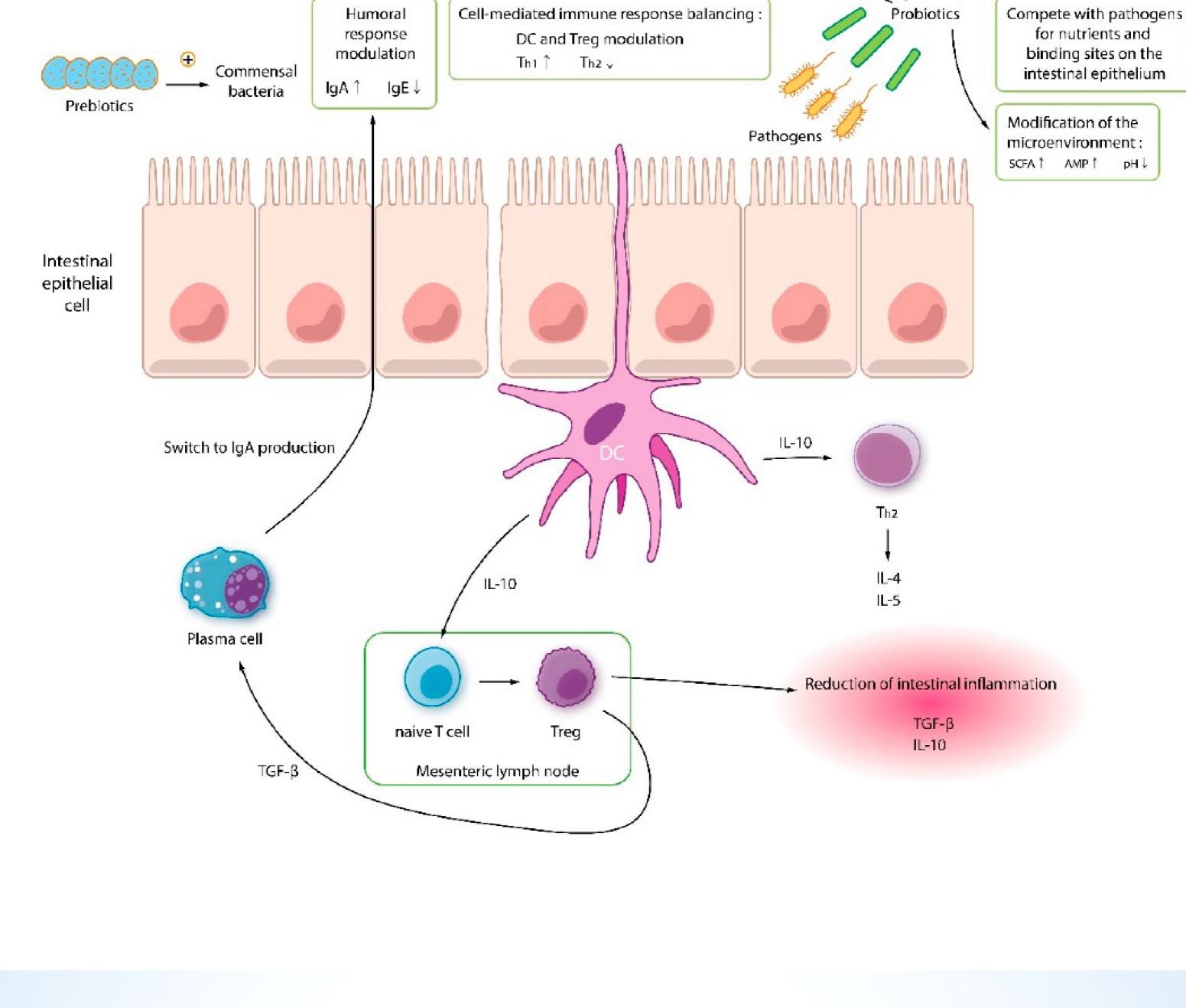
Gut microbiota and how it

RORyt+ cells, counterbalancing Th2-driven responses and helping shape immune responses*









Assessed for eligibility (n=107)

Clinical Evidence:

Oral Administration of Live Cells

(Woo et al. Ann Allergy Asthma Immunol 2010)



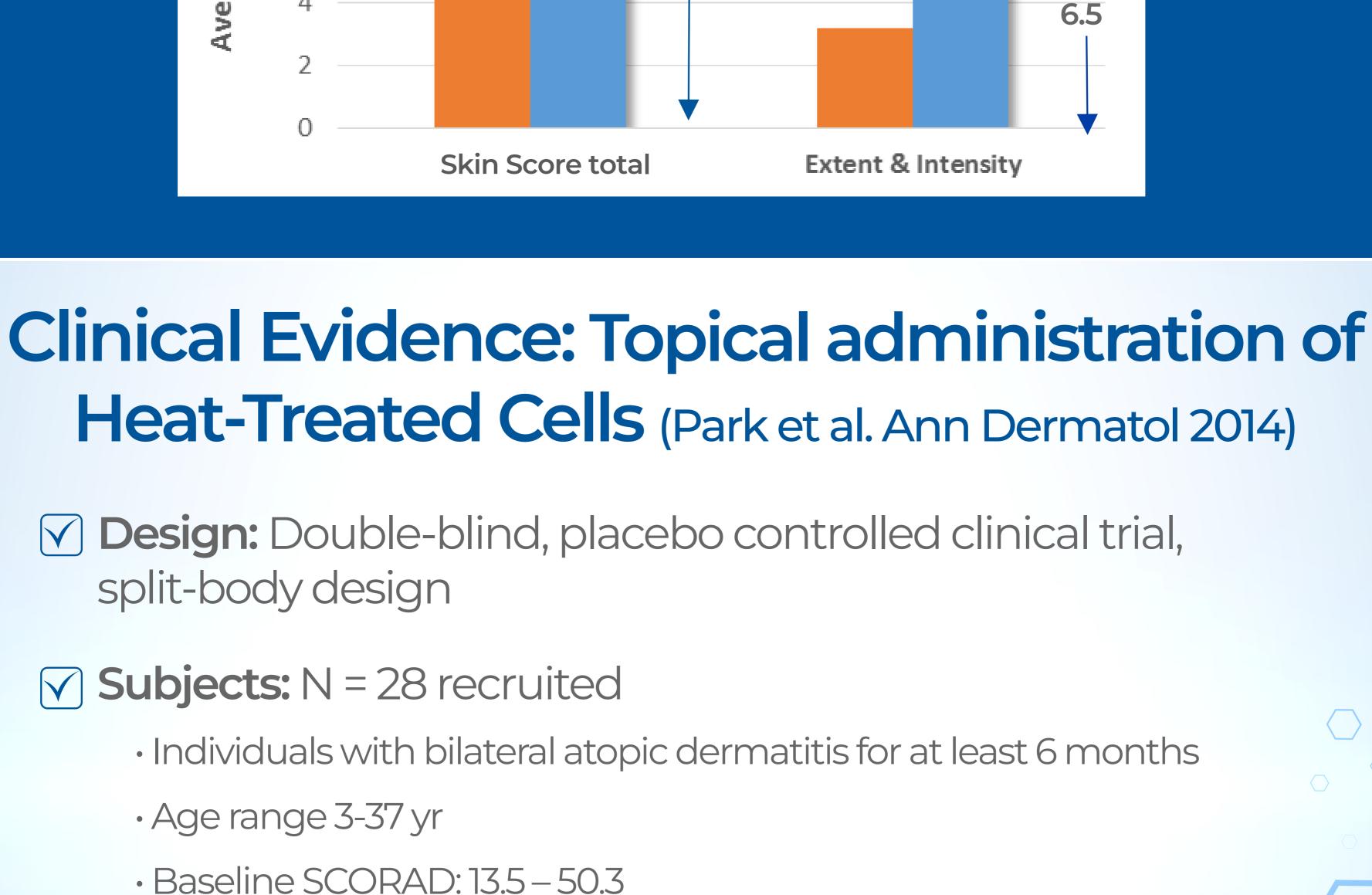
Mean improvement over placebo (9.6, 95%CI 3.8-15.3) doubles the average improvement in meta-analysis (5.7, 95%CI 4.2-7.3)

and to placebo

- Placebo
- 16 Average Score Improveme P=0.01 10

9.6

P=0.02



· Patients treated with cyclosporine or systemic steroids in the previous 4 weeks were excluded Intervention: Topical emollient containing 10% L. sakei Probio65® lysate (at 5x109 cfu/gr before lysis), used b.i.d. for 4

Results

Faster reduction in trans-epidermal water loss across time (P = 0.007)

Faster reduction in scoring of pruritus by means of a Visual Analog Scale

weeks, vs emollient without probiotic extract

- (p = 0.006)Efficacy has been replicated in randomized, placebo-controlled trials Oral application and topical emollients (cream or gel)
- Patent-protected strain Devoid of transmissible antibiotic resistance genes

The species Lactobacillus sakei has been evaluated by the European

Food Safety Authority (EFSA) Panel on Biological Hazards (BIOHAZ) and

· The QPS status is given if the taxonomic group does not raise safety

concerns or, if safety concerns exist, can be defined and excluded.

Supporting evidence from animal models, displaying effect on the

found to be suited for the Quality Presumption of Safety (QPS) status. • The QPS concept was developed to provide a harmonized generic preevaluation to support safety risk assessments of microorganisms

Heat-killed cells are efficacious both orally and topically

same immune biomarkers as in humans

- intentionally introduced into the food chain. The identity, body of knowledge, safety concerns and antimicrobial resistance of valid taxonomic units were assessed.
- This species has been present in the food supply as an article used for food in a form in which the food has not been chemically altered. **Disclaimer:** Kaneka is not responsible for the structure function claims used in

advertising of consumer packaged goods that contain Lactobacillus sakei

Probio65®. This communication is for informational purposes only, and its

content is not to be construed as advice regarding advertising claims. Before advertising consumer packaged goods that contain Lactobacillus sakei Probio65®, please consult a federal regulatory attorney experienced in the FTC and FDA regulations governing the advertising of dietary supplements.

Kalleka

*These statements have not been evaluated by the U.S. Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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