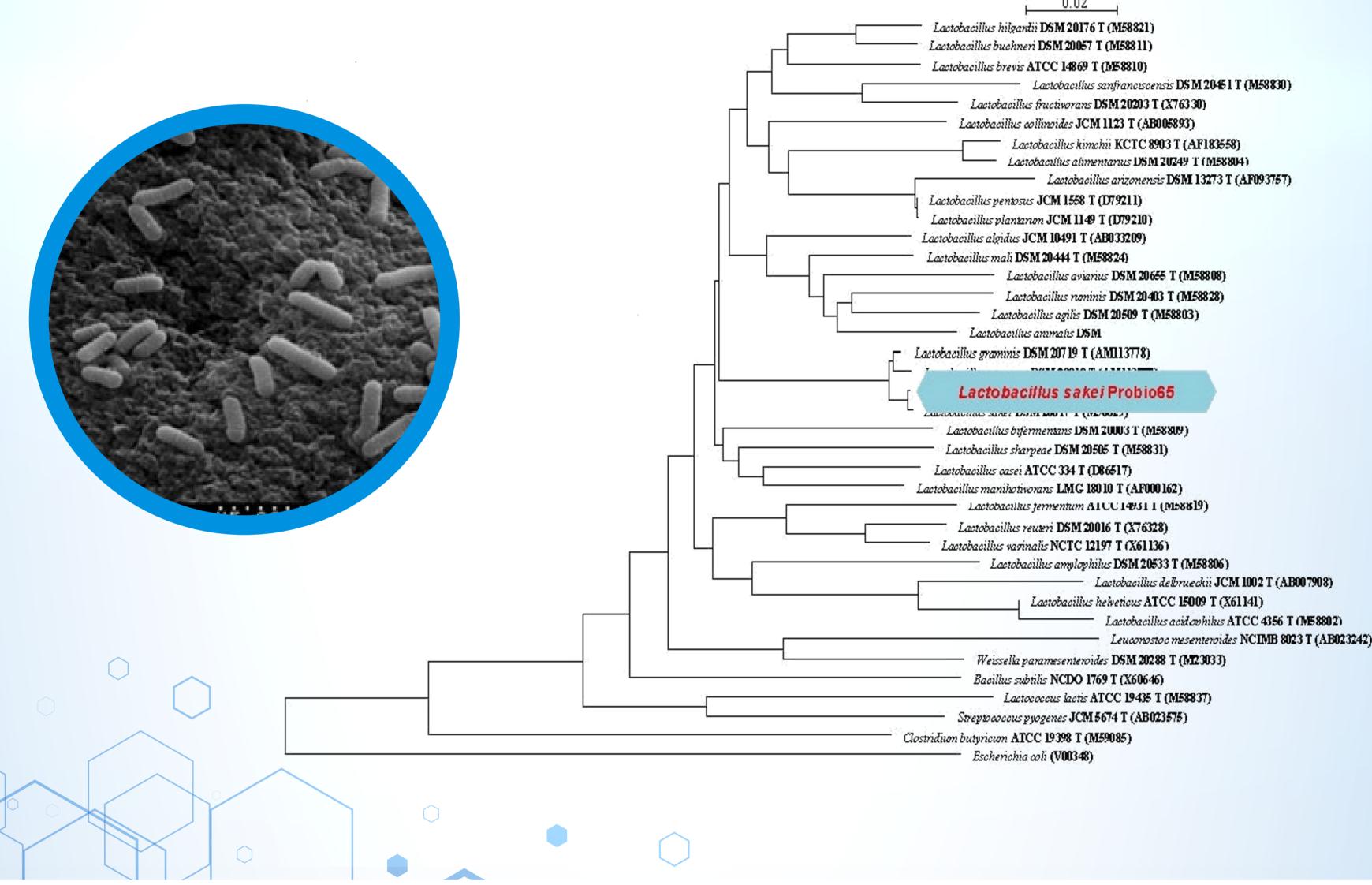
- Lack of antibiotic resistance*
- * per EFSA criteria



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

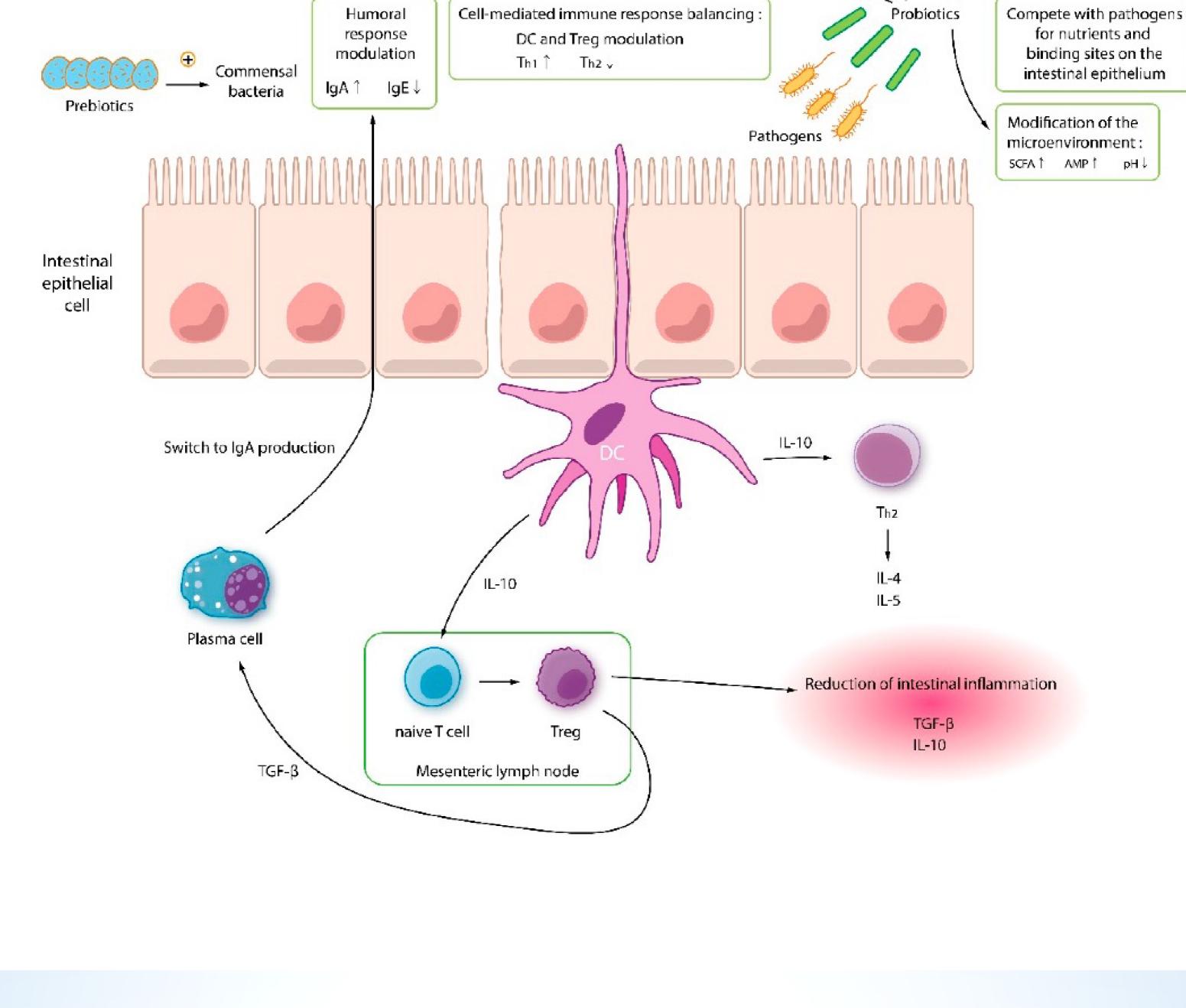
Gut microbiota and how it

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)



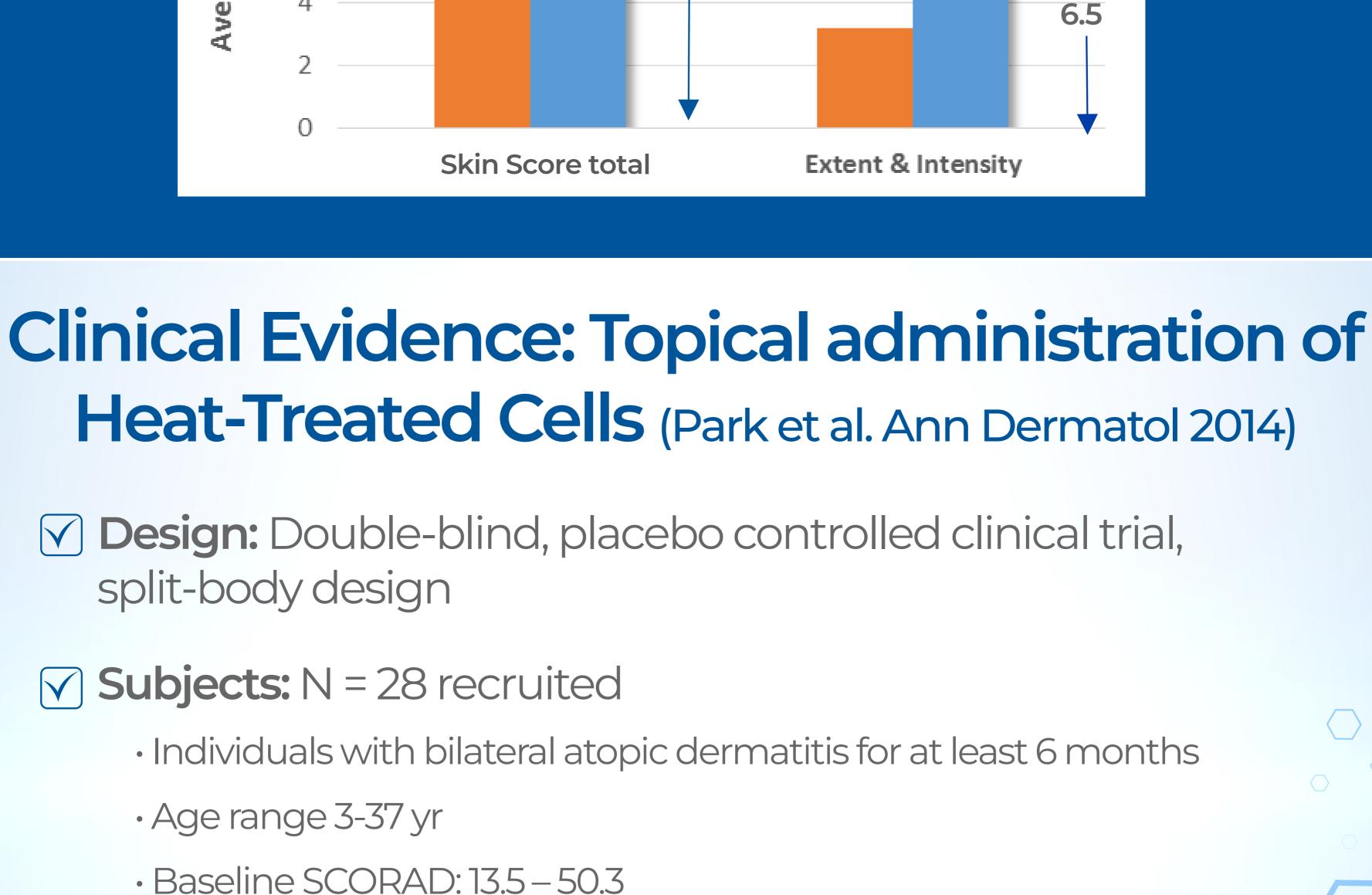
Mean improvement over placebo (9.6, 95%CI 3.8-15.3) doubles the average improvement in meta-analysis (5.7, 95%CI 4.2-7.3)

Placebo 16

and to placebo

Average Score Improveme P=0.01 10 P=0.02

9.6



· Patients treated with cyclosporine or systemic steroids in the previous

Probio65® lysate (at 5x109 cfu/gr before lysis), used b.i.d. for 4

Intervention: Topical emollient containing 10% L. sakei

weeks, vs emollient without probiotic extract

4 weeks were excluded

Faster reduction in scoring of pruritus by means of a Visual Analog Scale (p = 0.006)

Efficacy has been replicated in randomized, placebo-controlled trials

Supporting evidence from animal models, displaying effect on the

Results

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

Patent-protected strain Devoid of transmissible antibiotic resistance genes

Oral application and topical emollients (cream or gel)

Heat-killed cells are efficacious both orally and topically

same immune biomarkers as in humans

taxonomic units were assessed.

- The species Lactobacillus sakei has been evaluated by the European Food Safety Authority (EFSA) Panel on Biological Hazards (BIOHAZ) and
- preevaluation to support safety risk assessments of microorganisms intentionally introduced into the food chain. The identity, body of knowledge, safety concerns and antimicrobial resistance of valid

found to be suited for the Quality Presumption of Safety (QPS) status.

• The QPS concept was developed to provide a harmonized generic

· The QPS status is given if the taxonomic group does not raise safety concerns or, if safety concerns exist, can be defined and excluded. 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. *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. Kalleka

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