ATOPIC ECZEMA/DERMATITIS

TRALOKINUMAB PHASE 2B STUDY: EFFECTS OF THE ANTI-INTERLEUKIN-13 MONOCLONAL ANTIBODY ON STAPH. AUREUS SKIN COLONISATION AND SYSTEMIC LEVELS OF INFLAMMATORY BIOMARKERS IN PATIENTS WITH ATOPIC DERMATITIS

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Introduction: Tralokinumab, a fully human anti-interleukin-13 monoclonal antibody, has demonstrated significant improvements in Eczema Area Severity Score and in a greater percentage of patients with Investigator's Global Assessment score responses in a Phase 2b study (NCT02347176) in patients with atopic dermatitis (AD).

Objective: To examine the effects of tralokinumab on Staphylococcus aureus (SA) abundance and inflammatory biomarkers in adults with AD in an exploratory analysis of data from the Phase 2b study.

Materials and methods: 204 adults with moderate to severe AD were randomised 1:1:1:1 to receive subcutaneous tralokinumab 45, 150 or 300 mg, or placebo every 2 weeks for 12 weeks. Concomitant Class 3 (World Health Organization) topical corticosteroids were administered at least once daily during a 2-week run-in and as needed throughout the treatment and follow-up periods. Exploratory measurements included changes in SA abundance and serum biomarkers, including chemokine ligand 17 (CCL17), dipeptidyl peptidase-4 (DPP-4), periostin and immunoglobulin E (IgE), from baseline to week 12.

Results: At week 12, the percentage of SA-negative patients increased in a dose-dependent manner, reported in 50%, 55% and 62% of patients receiving tralokinumab 45, 150 and 300 mg, respectively, versus placebo (24%). Levels of CCL17 were reduced with tralokinumab 45 mg (−0.7%), 150 mg (−12.7%) and 300 mg (−40.0%), versus placebo (+37.4%). Similar dose-dependent reductions were seen with IgE (−6.80%, −17.0% and −22.3%, versus

+1.7%, respectively) and periostin (–23.3%, –26.6 and –31.3, versus +1.9%, respectively). DDP-4 levels were minimally affected by treatment (+8.1%, +8.7% and +7.3%, versus +3.9%, respectively). The most-frequent treatment-emergent adverse event related to study drug was upper respiratory tract infection (3.9% in both pooled tralokinumab and placebo groups).

Conclusions: Tralokinumab reduced SA abundance; levels of AD-associated serum biomarkers periostin, CCL17 and IgE were also reduced, while DPP-4 was increased to levels similar to placebo.