ATOPIC ECZEMA/DERMATITIS

DUPILUMAB PROVIDES CLINICALLY MEANINGFUL RESPONSES VERSUS PLACEBO: A POST HOC ANALYSIS OF A PHASE 3 TRIAL IN ADOLESCENTS WITH MODERATE-TO-SEVERE AD AMONG PATIENTS NOT ACHIEVING IGA SCORE OF 0/1

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Introduction: Dupilumab, a fully human monoclonal antibody inhibiting interleukin (IL)-4 and IL-13, is approved in several countries for the treatment of adults with inadequately controlled moderate to-severe atopic dermatitis (AD), and has also been evaluated in adolescent patients inadequately controlled with topical therapies.

Objective: To determine clinically meaningful responses (in signs, symptoms, or quality of life) to dupilumab treatment among adolescent patients with moderate-to-severe AD who did not achieve Investigator's Global Assessment (IGA) score of 0/1 (clear or almost clear) at Week 16.

Materials and Methods: In a double-blind, placebo-controlled, phase 3 trial, adolescent patients (≥12 to <18 years) were randomized 1:1:1 to subcutaneous dupilumab every 4 weeks (q4w; 300mg), every 2 weeks (q2w; 200mg if baseline weight <60kg, 300mg if ≥60kg), or placebo for 16 weeks (NCT03054428). Clinically meaningful responses were defined as: ≥50% improvement in Eczema Area and Severity Index (EASI-50) score, Peak

Pruritus Numerical Rating Scale (NRS) score improvement ≥3, Children's Dermatology Life Quality Index (CDLQI) score improvement ≥6. A composite endpoint was defined as clinically meaningful response in at least one of the above three endpoints.

Results: Of the 251 randomized patients, 69/84 (q4w), 62/82 (q2w), and 83/85 (placebo) patients had IGA>1 at Week 16. Among these patients at Week 16, EASI-50 was achieved by 44.9%, 48.4%, and 10.8% patients; Peak Pruritus NRS improvement ≥3 by 30.4%, 43.5%, and 7.2%; and CDLQI improvement ≥6 by 43.5%, 51.6%, and 16.9% in the q4w, q2w, and placebo groups, respectively
(P<0.001 vs placebo for all). 55.1% q4w, 74.2% q2w vs 21.7% placebo patients achieved the composite endpoint at Week 16 (P<0.0001). Dupilumab was generally well tolerated with an acceptable safety profile.

Conclusion: Among dupilumab-treated adolescent patients with IGA>1 at Week 16, a majority achieved clinically meaningful improvement in AD signs, symptoms, or quality of life vs placebo.