ATOPIC ECZEMA/DERMATITIS

LABORATORY SAFETY FINDINGS FOR DUPILUMAB IN ADOLESCENT PATIENTS WITH MODERATE-TO-SEVERE ATOPIC DERMATITIS INADEQUATELY CONTROLLED WITH OR INELIGIBLE FOR TOPICAL THERAPY

Elaine C. Siegfried [1] - Eric L. Simpson [2] - Amy S. Paller [3] - Lisa A. Beck [4] - Mark Boguniewicz [5] - Faisal A. Khokhar [6] - Ashish Bansal [6]

Saint Louis University And Cardinal Glennon Children's Hospital, Division Of Pediatric Dermatology, St. Louis, United States [1] - Oregon Health And Science University, Department Of Dermatology, Portland, United States [2] - Northwestern University Feinberg School Of Medicine, Department Of Dermatology, Chicago, United States [3] - University Of Rochester Medical Center, Department Of Dermatology, New York, United States [4] - National Jewish Health And University Of Colorado School Of Medicine, Department Of Pediatrics, Denver, United States [5] - Regeneron Pharmaceuticals, Inc., Medical Affairs, Tarrytown, United States [6]

Introduction: Dupilumab, a fully human monoclonal antibody inhibiting interleukin (IL)-4 and IL-13, is approved in many regions for the treatment of adults with inadequately controlled, moderate-to-severe atopic dermatitis (AD).

Objective: To report laboratory outcomes from a phase 3, randomized, double-blinded, placebo-controlled trial (AD-1526: NCT03054428) in adolescents (12–17 years) with moderate-to-severe AD inadequately controlled with topical therapies.

Materials and Methods: Patients were assigned 1:1:1 to dupilumab 300mg every 4 weeks (q4w), 200/300mg every 2 weeks (q2w), or placebo q2w for 16 weeks (Wks). Mean changes in laboratory values from baseline through Wk16 were assessed.

Results: Baseline clinical and laboratory characteristics were similar for 250 patients in 3 treatment groups (q4w, n=83; q2w, n=82; placebo, n=85). The only notable difference in the dupilumab groups compared with placebo was a transient increase in eosinophil counts, with the greatest mean changes at Wk8 (q4w/q2w vs placebo, 0.177/0.189 vs –0.086 x109/L). These increases returned to baseline by Wk16 and were not associated with clinical consequences. Mean changes from baseline through Wk16 were not different among groups for: leukocytes (–0.36/0.01 vs –0.27 x109/L), hemoglobin (–0.8/–1.2 vs –0.8 g/L), alanine aminotransferase (–2.9/–3.4 vs –2.2 U/L), alkaline phosphatase (5.3/12.4 vs

–5.7 U/L), bilirubin (–0.149/0.432 vs 0.212 µmol/L), creatinine (<0.1/–1.3 vs –1.1 µmol/L), and blood urea nitrogen (0.174/0.051 vs –0.055 mmol/L). Efficacy endpoints were statistically superior in both dupilumab groups at Wk16 compared to baseline: Investigator's Global Assessment 0/1 (P=0.0007/P<0.0001, q4w/q2w vs placebo); ≥75% improvement in Eczema Area and Severity Index score (EASI; P <0.0001 vs placebo); mean percentage change in EASI (P<0.0001 vs placebo).

Conclusions: Although transient increases in eosinophil counts were noted, adolescents with moderate to-severe AD treated with dupilumab did not exhibit any clinically meaningful changes vs placebo in laboratory parameters. These findings suggest that treatment with dupilumab does not require laboratory testing before initiation/during treatment.