Baseline Serum Biomarkers Do Not Predict Dupilumab Treatment Response in Adults With Moderateto-Severe Atopic Dermatitis

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Background: Previous analyses based on short-term, phase 2 studies reported that baseline biomarkers do not correlate with clinical outcomes following dupilumab treatment in patients with atopic dermatitis (AD). This new analysis based on 16-week, phase 3 studies reports whether pre-treatment levels of common serum biomarkers can predict treatment response to dupilumab in adults with moderate-to-severe AD.

Methods: LIBERTY AD SOLO 1 and 2 (NCT02277743, NCT02277769), two randomized, double-blind studies, included patients \geq 18 years-old with moderate-to-severe AD treated with dupilumab 300 mg every 2 weeks or placebo for 16 weeks. Correlation between change in Eczema Area and Severity Index (EASI) and log of baseline IgE, CC chemokine ligand 17 (CCL17; previously referred to as thymus and activation-regulated chemokine [TARC]) and lactate dehydrogenase (LDH) at baseline was assessed using Spearman's correlation coefficient (ρ).

Results: At Week 16, change in EASI showed little correlation with baseline total IgE (Spearman's correlation coefficient $[\rho] = -0.14$, n = 370 for dupilumab; $\rho = -0.03$, n = 202 for placebo), baseline

CCL17 (ρ = -0.28, n = 369 for dupilumab; ρ = -0.05, n = 201 for placebo), or baseline LDH (ρ = -0.30, n = 370 for dupilumab; ρ = -0.08, n = 202 for placebo). Overall safety was consistent with the known dupilumab safety profile.

Conclusion: Baseline levels of total IgE, CCL17 and LDH do not predict treatment response to dupilumab, as measured by EASI, in adults with moderate-to-severe AD.

Keywords: atopic dermatitis, dupilumab, predictive, biomarkers, clinical outcomes

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