Clinical measures of improvement in atopic dermatitis are correlated with reductions in relevant biomarkers in patients treated with lebrikizumab

Emma Guttman-Yassky¹, Angela Okragly², Zhe Sun², Brian J. Nickoloff², Chitra R Natalie², Gaia Gallo², Eric Wolf², Kilian Eyerich³, Monica Aparici⁴, Robert J. Benschop²

¹Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, USA; ²Eli Lilly and Company, Indianapolis, USA; ³Department of Dermatology, Medical Center, University of Freiburg, Germany; ⁴Almirall S.A., Barcelona, Spain

Introduction: In ADvocate1 (NCT04146363) and ADvocate2 (NCT04178967), lebrikizumab demonstrated statistical superiority vs. placebo in patients with moderate-to-severe atopic dermatitis (AD). The objective of this analysis is to test for correlations between improvements in clinical outcomes and reductions in AD-relevant serum biomarkers during ADvocate1 and ADvocate2.

Objectives: To assess the correlation between clinical measures of atopic dermatitis (AD) and AD-specific biomarkers at baseline; and to assess the correlation between clinical measures of AD and changes in AD-specific biomarkers after treatment with lebrikizumab.

Methods: Full details of these studies were previously reported. Protein biomarkers were determined in available serum samples from patients receiving lebrikizumab 250 mg every 2 weeks (n=72) or placebo (n=36). Tested biomarkers included: IL-13 (baseline only), CCL2, CCL4, CCL11, CCL13, CCL17 (TARC), CCL22, CCL26 (eotaxin-3), CXCL10, total IgE, IL-4, IL-5, and periostin. Baseline biomarker levels and baseline clinical endpoints were compared using a Spearman correlation. A repeated measures correlation analysis was used to characterize paired measurement of within-patient
biomarker levels and clinical endpoints at baseline, week 4, week 16, and week 52. Clinical measures of AD included Investigator’s Global Assessment (IGA), Eczema Area and Severity Index (EASI), and Pruritus Numeric Rating Scale (NRS).

**Results:** At baseline, EASI score was positively correlated with IL-13, periostin, IL-5, IgE, CCL13, CCL17, CCL22 and CCL26 (correlation coefficient >0.3, p<0.05), but not IL-4. During the studies, improvements in EASI, IGA, and Pruritus NRS were each correlated with reductions in periostin, CCL13, CCL17, CCL22, and CCL26 (correlation coefficient >0.3, p<0.05). Improvement in IGA was also correlated with a reduction in IgE (correlation coefficient >0.3, p<0.05).

**Conclusions:** Clinical measures of improvement in the signs and symptoms of AD are correlated with reductions in AD biomarkers in patients treated with lebrikizumab.

**Keywords:** Atopic dermatitis, Biomarkers, Eczema Area and Severity Index, Lebrikizumab, Pruritus Numeric Rating Scale.

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