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LEBRIKIZUMAB PROVIDES CLINICALLY MEANINGFUL RESPONSE IN FACE AND HANDS IN ADULTS AND ADOLESCENTS WITH MODERATE-TO-SEVERE ATOPIC DERMATITIS: ADHOPE 1 STUDY

L. Stingeni¹, C. Vestergaard², J. Seneschal^{3/4}, S. Weidinger⁵, A. Wollenberg^{6/7/8}, A. Irvine⁹, H. Agell¹⁰, J. Valls Bancells¹⁰, V. Sapena¹⁰, D. Thaçi⁷

¹Dermatology Section, Department of Medicine and Surgery, University of Perugia, Italy; ²Department of Dermatology and Venerology, Aarhus University Hospital, Aarhus, Denmark; ³Department of Dermatology, University of Bordeaux, Bordeaux, France; ⁴Department of Dermatology and Pediatric Dermatology, National Reference Center for Rare Skin Disorders, Hospital Saint-André, Bordeaux, France; ⁵Department of Dermatology and Allergy, University Hospital Schleswig-Holstein, Kiel, Germany; ⁶University Medical Center of Augsburg, Augsburg, Germany; ⁷Institute and Comprehensive Center for Inflammatory Medicine at the University of Lübeck, Lübeck, Germany; ⁸Department of Dermatology and Allergology, LMU Hospital, Munich, Germany; ⁹Department of Clinical Medicine, Trinity College Dublin, Dublin, Ireland; ¹⁰Almirall S.A., Barcelona, Spain

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Most patients (pts) with atopic dermatitis (AD) have face and/or hands involvement, posing a major psychological burden(1). Lebrikizumab (LEB), a monoclonal antibody that selectively targets interleukin-13, is approved for moderate-to-severe (mod-sev) AD(2-4). We report LEB efficacy in face and hands from ADhope 1 (NCT05990725). ADhope 1 was a 24-Week(W), open-label study in adults and adolescents (12-17 years, ≥ 40 kg), Eczema Area and Severity Index (EASI) ≥ 12 , Investigator's Global Assessment (IGA) ≥ 3 , $\geq 10\%$ body surface area AD involvement, who were not adequately controlled with topical therapies. Prior dupilumab use was allowed. Pts received 500mg at baseline (BL) and W2, then 250mg every 2 weeks (Q2W) until W16, then 250mg Q4W until W24. Topical corticosteroid use was allowed. Outcomes included Face IGA 0/1 with ≥ 2 -point improvement from BL, and Face IGA ≥ 1 -point improvement from BL in pts with Face IGA ≥ 2 at BL, and percent change from BL in modified Total Lesion Symptom Score (mTLSS) to assess response in hands. Treatment discontinuation due to lack of efficacy was classed as non-response; other discontinuations and missing data were handled by multiple imputation. Data collected after prohibited medication use were included. Efficacy was assessed in 247/260 enrolled pts (13 pts excluded due to quality issues). At BL, mean age (standard deviation [SD])=32.8 (14.1) years, 61.1% male,

8.5% had prior dupilumab exposure. Mean (SD) EASI=23.1 (9.0), mean (SD) Pruritus Numerical Rating Scale=6.7 (1.6), IGA scores of 3 (moderate) and 4 (severe) were reported in 74.1% and 25.9% of pts, respectively. 69.6% of pts had Face IGA ≥ 2 (15.8% Face IGA=2, mild; 42.5% Face IGA=3, moderate; 11.3% Face IGA=4, severe). 64.0% had AD in their hands (mean [SD] BL mTLSS=9.7 [4.1]). Of pts with Face IGA ≥ 2 at BL (n=172), 79.1% achieved Face IGA ≥ 1 -point improvement at W24 and 44.8% achieved Face IGA 0/1 with ≥ 2 -point improvement at W24 (Fig. 1). Face response correlated with overall body response. Of pts with AD in the hands at BL (n=158), mean percent change from BL in mTLSS progressively increased over time and was -66.3% at W24. LEB provided improvements in AD affecting the face and/or hands. Almost half of the population achieved clear/almost clear skin on the face within 24W of treatment. Findings indicate that LEB is an effective treatment option for pts with mod-sev AD, including those with facial and hand involvement. This study was funded by Almirall, S.A.

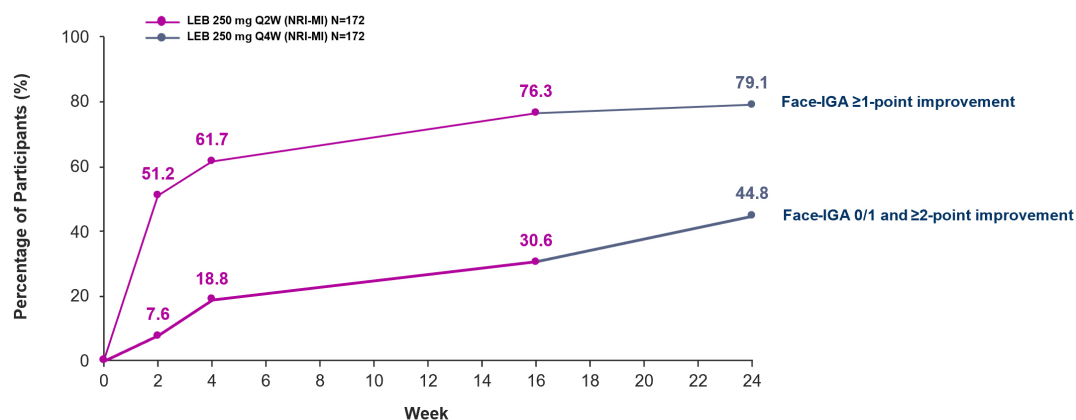
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Figure 1. Face Investigator's Global Assessment 0/1 with ≥ 2 -point improvement and Face Investigator's Global Assessment ≥ 1 -point improvement through Week 24 in patients with Face Investigator's Global Assessment ≥ 2 at baseline, modified full analysis set, non-responder imputation-multiple imputation



Restricted to patients with Face IGA ≥ 2 at baseline. Treatment discontinuation due to lack of efficacy was considered as non-response, while treatment discontinuations due to any other reason, as well as any other missing data, were handled through multiple imputation. Data collected after use of prohibited medication was included in the analysis. IGA: Investigator's Global Assessment; LEB: lebrikizumab; mFAS: modified full analysis set; MI: multiple imputation; NRI: non-responder imputation; QXW: every X weeks; W: Week.