

Dupilumab Treatment Improves Health-Related Quality of Life in Children Aged ≥ 6 to < 12 Years With Severe Atopic Dermatitis

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Background: The Children's Dermatology Life Quality Index (CDLQI, scores ranging 0–30) is a 10-item questionnaire assessing patient/caregiver-reported impact of atopic dermatitis (AD) on health-related quality of life (HRQoL), which is severely impacted in young AD patients. We report the effect of 16-week treatment with dupilumab and concomitant topical corticosteroids (TCS) on CDLQI scores in children with severe AD.

Methods: In LIBERTY AD PEDS (NCT03345914), a multicenter, phase 3 trial, 367 patients aged ≥ 6 to < 12 years were randomized 1:1:1 to receive subcutaneous dupilumab every 2 (q2w) or 4 weeks (q4w), or placebo, all with concomitant medium-potency TCS. We report baseline CDLQI \pm standard deviation (SD) and least squares mean change from baseline in total CDLQI \pm SD for FDA-approved doses only (300 mg q4w [300q4w] + 600 mg loading dose if baseline weight < 30 kg; 200 mg q2w [200q2w] + 400 mg loading dose if ≥ 30 kg, n=61/59) and weight-matched placebo (n=61/62) with nominal P values (*P < 0.05 ; ***P < 0.001 ; ****P < 0.0001) vs corresponding placebo. A within-person change of ≥ 6 -points in CDLQI is considered clinically meaningful.

Results: At baseline, mean CDLQI scores suggested a “very large effect” of AD on patients' lives (300q4w+TCS: 16.9 \pm 8.1; placebo+TCS < 30 kg: 16.1 \pm 6.9; 200q2w+TCS: 13.0 \pm 6.3; placebo+TCS ≥ 30 kg: 13.2 \pm 7.7). Dupilumab+TCS significantly improved total CDLQI scores by Week 2 (300q4w+TCS: $-6.9 \pm 0.6^{***}$, placebo+TCS < 30 kg: -3.7 ± 0.6 ; 200q2w+TCS: $-5.9 \pm 0.6^*$, placebo+TCS ≥ 30 kg: -3.9 ± 0.6) and improved further at Week 16 (300q4w+TCS: $-10.7 \pm 0.7^{****}$, placebo+TCS < 30 kg: -6.3 ± 0.7 ; 200q2w+TCS: $-10.5 \pm 0.7^{****}$, placebo+TCS ≥ 30 kg: -6.4 ± 0.7). The safety profile in this study was consistent with the known dupilumab safety profile.

Conclusions: Dupilumab with concomitant TCS significantly improved HRQoL measured by CDLQI in children with severe AD compared to placebo+TCS.