Dupilumab Induces Rapid and Sustained Improvement in Clinical Signs in Children With Severe Atopic Dermatitis

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Background: Dupilumab, a fully human monoclonal antibody that blocks the shared receptor component for interleukin-4 and interleukin-13, received FDA-approval in 2020 for children aged ≥ 6 to < 12 years with uncontrolled moderate-to-severe atopic dermatitis (AD). We analyzed the effect of dupilumab on AD signs (erythema, infiltration/papulation, excoriations, lichenification) by anatomical region in children aged ≥ 6 to < 12 years with severe AD.

Methods: In LIBERTY AD PEDS (NCT03345914), a phase-3 trial, 367 patients aged ≥ 6 to < 12 years received subcutaneous dupilumab every 2 weeks (q2w; 100 mg if baseline weight < 30 kg, 200 mg if ≥ 30 kg), every 4 weeks (q4w, 300 mg), or placebo, for 16 weeks. All patients received concomitant medium-potency topical corticosteroids (TCS). Here we only report the effect of FDA-approved doses of dupilumab (300 mg q4w if baseline weight < 30kg [n = 61] or 200 mg q2w if ≥ 30kg [n = 59]) and weight-matched placebo (n = 61 / 62, respectively). Least squares (LS) mean percent change in Eczema Area and Severity Index (EASI) components by anatomical region is reported. The last observation carried forward method was used with censoring after rescue treatment use.

Results: Significant improvements in all signs across all body regions occurred as early as Week 4. LS mean percent changes in EASI erythema score at Week 16 vs corresponding placebo + TCS for the head and neck region were −67.9 vs −39.4 ($P < 0.001$) for the < 30 kg groups and −75.2 vs −35.7 ($P < 0.0001$) for ≥ the 30 kg groups. LS mean % changes in EASI erythema score for the trunk region in the < 30 kg / ≥ 30 kg groups vs placebo + TCS were −87.6 vs −44.6 / −81.4 vs −49.0 (both $P < 0.0001$); for upper extremities, −82.5 vs −36.0 / −76.1 vs −40.4 (both $P < 0.0001$); and for lower extremities, −82.7 vs −39.6 / −72.2 vs −41.4 (both $P < 0.0001$). The 4 EASI components showed overall synchrony of improvements with relative lead in reduction of excoriations and slight relative lag in lichenification change, as would be clinically expected. However, at Week 16 near-uniform significant benefits were seen for all signs in all anatomical regions. Dupilumab was generally well tolerated with an acceptable safety profile.

Conclusion: Dupilumab induced rapid and consistent improvement in all clinical signs and anatomical regions in children with severe AD.