Dupilumab Significantly Improves Atopic Dermatitis in Children Aged ≥6 to <12 years: Results From Phase 3 Trial (LIBERTY AD PEDS)

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Background: Dupilumab is approved in the USA for subcutaneous administration every 2 weeks (q2w) for the treatment of patients aged ≥12 years with moderate-to-severe atopic dermatitis (AD) inadequately controlled with topical prescription therapies or when those therapies are not advisable. We present dupilumab efficacy and safety data in children aged ≥6 to <12 years with severe AD.
Methods: In this double-blind trial (NCT03345914), children aged ≥6 to <12 years (minimum weight 15kg) with severe AD (Investigator's Global Assessment [IGA] score=4) were randomized 1:1:1 to subcutaneous dupilumab q2w (100mg if baseline weight <30kg, 200mg if ≥30kg), every 4 weeks (q4w, 300mg regardless of weight), or placebo for 16 weeks. From Day −14, all patients initiated standardized treatment with medium-potency topical corticosteroids (TCS).
Results: 367 patients were randomized (q2w/q4w/placebo groups, n=122/n=122/n=123). At Week 16, 29.5%/32.8%/11.4% of patients receiving q2w/q4w/placebo achieved IGA scores of 0/1 (clear/almost clear); 67.2%/69.7%/26.8% achieved ≥75% improvement from baseline in Eczema Area and Severity Index (EASI). Least squares (standard error) mean percent change in EASI and Peak Pruritus Numerical Rating Scale were −78.4(2.35)/−82.1(2.37)/−48.6(2.46) and −57.0 (2.77)/−54.6 (2.89)/−25.9(2.90), respectively (*P*<0.001 vs placebo for all comparisons). Serious adverse events (AEs) and AE-related treatment discontinuations were rare; injection-site reactions and conjunctivitis were more common with dupilumab than with placebo.

Conclusion: Dupilumab+TCS showed clinically meaningful and statistically significant improvement in AD signs and symptoms in children aged ≥6 to <12 years with severe AD and was well tolerated with no new safety signals compared with adults and adolescents.

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