Rapid Itch Improvement in Children With Severe Atopic Dermatitis Treated With Dupilumab: A Phase 3 Subset Analysis

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Introduction: In LIBERTY AD PEDS (NCT03345914), a 16-week double-blind, placebo-controlled, phase 3 trial, dupilumab significantly improved atopic dermatitis (AD) signs and symptoms in children with severe AD. Here, we assess time to onset of pruritus improvement in children with severe AD treated with dupilumab FDA-approved doses.

Methods: Children aged ≥6–<12 years were randomized to dupilumab 300mg every 4 weeks (300q4w, baseline weight <30kg; 600mg loading dose), 200mg every 2 weeks (200q2w, baseline weight ≥30kg; 400mg loading dose), or placebo. All patients received concomitant medium-potency topical corticosteroids (TCS). We report change from baseline in daily Peak Pruritus Numerical Rating Scale (NRS) scores and proportion of patients who achieved ≥4-point improvement from baseline in Peak Pruritus NRS.

Results: 243 patients were included in this post hoc analysis (300q4w+TCS/ placebo+TCS<30kg/ 200q2w+TCS/ placebo+TCS≥30kg, n=61/61/59/62). Mean percent change from baseline (standard error) in daily Peak Pruritus NRS decreased after a single dose of dupilumab, as early as Day 8 in the dupilumab 300q4w group vs control (–13.8% [2.9] vs –5.1% [2.9]; $P<0.05$) and Day 16 for children treated with dupilumab 200q2w vs control (−22.1% [3.4] vs −12.6% [3.3]; $P<0.05$). A higher proportion of dupilumab-treated patients showed clinically meaningful response (≥4-point improvement) in Peak Pruritus NRS vs control, as early as Week 3 in the dupilumab 300q4w group (14.8% vs 3.3%; $P<0.05$) and Week 5 in the dupilumab 200q2w group (28.1% vs 12.9%; $P<0.05$).

Conclusion: Dupilumab+TCS treatment provided rapid and clinically meaningful improvement in intensity and frequency of itch in children with severe AD.