Dupilumab Monotherapy Provides Long-Term Control and Prevents Flares in Adults With Moderate-to-Severe Atopic Dermatitis Optimally Responding at Week 16

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory systemic disease requiring long-term management to achieve disease control. The long-term efficacy and safety of dupilumab, a targeted biological therapy approved for the treatment of adults with moderate-to-severe AD, have been reported in combination with topical corticosteroids (TCS) (LIBERTY AD CHRONOS: NCT02260986). Dupilumab every 2 weeks (q2w) + TCS has been shown to prevent disease exacerbations (flares) in more than 80% of patients treated in CHRONOS. Here we assess the incidence of flares in patients over 36 weeks of maintenance treatment with dupilumab q2w monotherapy after an optimal response at Week 16 of dupilumab monotherapy.

Materials & Methods: Adult patients with moderate-to-severe AD who had previously participated in SOLO 1/2 (NCT02277743 and NCT02277769) and had achieved a 75% reduction from baseline in Eczema Area and Severity Index (EASI-75) and/or an Investigator's Global Assessment (IGA) score of 0/1 at Week 16 were enrolled in this randomized, long-term, double-blind, placebo-controlled phase 3 study (LIBERTY AD SOLO-CONTINUE, NCT02395133). Here we show data for patients treated in SOLO-CONTINUE with 300 mg dupilumab monotherapy q2w or placebo for an additional 36 weeks. Flares were defined as the worsening of disease requiring initiation or escalation of rescue treatment.

Results: At SOLO-CONTINUE baseline (Week 16 of parent study), patients treated with dupilumab who met response criteria were re-randomized to either continuing dupilumab q2w (n = 80) or switched to placebo (n = 82). The proportion of patients with a flare event up to Week 52 was significantly lower for patients receiving dupilumab q2w compared with placebo (20.0% vs 48.2%; *P* = 0.0004). Dupilumab was generally well tolerated, with an acceptable safety profile.

Conclusions: A majority (80%) of patients who had achieved IGA 0/1 or EASI-75 response after 16 weeks of treatment and continued on dupilumab 300 mg q2w monotherapy remained flare-free during an additional 36 weeks of treatment. Compared with placebo, dupilumab monotherapy significantly prevents flares over 1 year in most adults with moderate-to-severe AD who have optimally responded at Week 16 of treatment.