Dupilumab Monotherapy Provides 1 Year Sustained Response in Adults With Moderate-to-Severe Atopic Dermatitis Optimally Responding at Week 16, With no Need of Concomitant Topical Steroids

Margitta Worm[1], Eric L. Simpson[2], Diamant Thaçi[3], Lisa A. Beck[4], Amy Praestgaard[5], Genevieve Wortzman-Show[6], Ana B. Rossi[5]

[1]Charité-Universitätsmedizin Berlin, Berlin, Germany; [2]Oregon Health and Science University, Portland, OR, USA; [3]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [4]University of Rochester Medical Center, Rochester, NY, USA; [5]Sanofi Genzyme, Cambridge, MA, USA; [6]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA

Introduction & Objectives: The efficacy and safety of dupilumab with topical corticosteroids (TCS) in the treatment of adults with moderate-to-severe atopic dermatitis (AD) over 1 year have been assessed in the double-blind, randomized, placebo-controlled study LIBERTY AD CHRONOS (NCT02260986). In the SOLO-CONTINUE study (monotherapy, randomized, placebo controlled; NCT02395133), the maintenance of efficacy and safety of dupilumab was evaluated for an additional 36 weeks in patients who had achieved either an Investigator's Global Assessment (IGA) score of 0/1 (clear/almost clear skin) and/or a 75% reduction from baseline in Eczema Area and Severity Index (EASI-75) at Week 16 of SOLO 1 or SOLO 2. Here we report the percentage of patients treated over an additional 36 weeks of dupilumab monotherapy who did not require TCS (rescue treatment).

Materials & Methods: Adult patients with moderate-to-severe AD who had previously participated in SOLO 1/2 (NCT02277743 and NCT02277769) and had achieved EASI-75 and/or an IGA score of 0/1 at Week 16 were enrolled into this randomized, long-term, double-blind, placebo-controlled phase 3 study (LIBERTY AD SOLO-CONTINUE, NCT02395133). In SOLO-CONTINUE, TCS use of any potency was considered rescue treatment; patients who received rescue treatment were considered treatment failures. Here we show data for patients treated in SOLO-CONTINUE who continued 300 mg dupilumab monotherapy every 2 weeks (q2w) or who were randomized to placebo for an additional 36 weeks.

Results: At SOLO-CONTINUE baseline (Month 4), patients were randomized to continue dupilumab 300 mg q2w (n = 80) monotherapy or switched from dupilumab treatment to placebo (n = 82). Use of any potency of topical steroid was considered rescue treatment, and failure to respond. At Month 12, only 10% of dupilumab monotherapy patients required TCS rescue compared with 33% of patients who switched to placebo at Week 16 ($P = 0.0013$). In the small percentage of patients treated with dupilumab who used TCS, most used low-to-moderate potency steroids. Dupilumab was generally well tolerated with an acceptable safety profile.

Conclusions: Most patients (90%) who achieved optimal response with 16 weeks of dupilumab monotherapy every two weeks have remained TCS-free over 36 additional weeks of treatment.