

Dupilumab Treatment Provides Improvements in Signs of Atopic Dermatitis (AD) at Week 100 in Adult Patients With Moderate-to-Severe AD Who Did Not Achieve $\geq 75\%$ Reduction in Eczema Area and Severity Index at Week 16

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Background: Atopic dermatitis (AD) is a chronic inflammatory skin disease that may require long-term management. Here, we report dupilumab efficacy up to week 100 in an open-label extension (OLE) study (NCT01949311) of adult patients with moderate-to-severe AD who did not have an improvement of $\geq 75\%$ in Eczema Area and Severity Index (EASI-75) or an Investigator's Global Assessment (IGA) score of 0/1 at week 16 during their parent study.

Methods: Patients included in this analysis participated in parent studies LIBERTY AD SOLO 1 or 2 (SOLO1&2; NCT02277743, NCT02277769) and were subsequently enrolled in LIBERTY AD OLE, assessing long-term safety and efficacy, in which all patients received dupilumab 300 mg weekly (qw). Included in this analysis were patients who previously received dupilumab in SOLO 1&2 and who subsequently enrolled in OLE, but who did not achieve either EASI-75 or IGA 0/1 at week 16 of SOLO1&2.

Results: Enrolled in SOLO 1&2 were 460, 457, and 462 patients in the placebo, dupilumab 300 mg q2w, and dupilumab 300 mg qw groups, respectively. Most patients who achieved the primary endpoints of SOLO 1&2 continued into SOLO-CONTINUE (NCT02395133); most patients who did not achieve the primary endpoints of SOLO 1&2 entered OLE. Overall, 213/178 patients entered OLE from SOLO 1&2 (receiving dupilumab 300 mg q2w, and dupilumab 300 mg qw in SOLO 1&2, respectively). Of these patients, $\geq 91.5\%$ did not achieve either EASI-75 or IGA 0/1 at week 16 of SOLO 1&2 and thus were included in this analysis. Proportions of patients with EASI-75 at week 100 of the OLE were 91.0% and 91.1% for the SOLO1&2 dupilumab 300 mg q2w and dupilumab 300 mg qw treatment groups, respectively. Similarly, at week 100 of the OLE, proportions of patients with IGA scores of 0 or 1 were 44.8% and 49.0% for the patients who received dupilumab 300 mg q2w and dupilumab 300 mg qw, respectively, in SOLO1&2.

Conclusions: Among patients with moderate-to-severe AD not achieving EASI-75 or IGA 0/1 at week 16 in SOLO 1&2, a large proportion achieved these respective endpoints after continued treatment with dupilumab 300 mg qw. These OLE data suggest that long-term treatment with dupilumab improves AD signs in patients who do not respond optimally in the short term, independent of parent-study treatment dose.

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