Dupilumab Provides Long-Term Efficacy Over 2.5 Years in Adults With Moderate-to-Severe Atopic Dermatitis

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Background: Here we explore the long-term efficacy of dupilumab in patients (pts) that optimally responded at Week (Wk) 16 of the double-blind, placebo-controlled studies SOLO 1 and 2 and subsequently enrolled in SOLO-CONTINUE for 36 weeks (wks) of maintenance with dupilumab monotherapy (weekly [qw]/every 2 weeks [q2w]) or placebo (PBO), followed by 76 wks of dupilumab qw in an open-label extension (OLE) study.

Methods: Adult pts 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 Wk16 were enrolled in SOLO-CONTINUE (NCT02395133) for an additional 36 wks, followed by 76 wks in the OLE (NCT01949311). Here we analyse pts who maintained response, defined as proportion of pts achieving IGA ≤ 2.

Results: At SOLO-CONTINUE baseline (Wk16 of parent study), pts on 300mg dupilumab q2w or qw achieving IGA 0/1 and/or EASI-75 were re-randomized to continuing q2w, qw, or PBO of which 73 (q2w), 81 (qw) and 75 (PBO) pts were subsequently treated with dupilumab 300mg qw for an additional 76 wks. Pts maintained on dupilumab monotherapy over an additional 36 wks maintained response as measured by the proportion of pts achieving IGA ≤ 2, with similar results for pts treated qw or q2w (88.9%/86.3% vs 44.0% for pts moving to PBO; $P<0.0001$) or EASI-75 (86.4%/87.7% vs 48.0%; $P<0.0001$) by Wk52. When pts transitioned to OLE, both pts who continued to receive dupilumab 300mg qw and those transitioning from q2w to qw sustained their responses; pts on PBO transitioning to dupilumab 300mg qw showed rapid improvement within the first month, which was maintained through to Wk128, as measured by the proportion of pts achieving IGA ≤ 2 (93.3%/95.1%/97.3%) or EASI-75 (92.0%/100%/97.3%). Dupilumab was generally well tolerated, with safety consistent with what was observed in SOLO 1/2.

Conclusions: Pts achieving EASI-75 and/or IGA 0/1 at Wk16 in SOLO 1/2 demonstrated sustained response over an additional 36 wks in SOLO-CONTINUE in both the dupilumab 300mg qw and q2w monotherapy groups, and additional 76 wks on dupilumab 300mg qw in OLE. Pts re-randomized from dupilumab 300mg qw/q2w to PBO showed progressively slow loss of efficacy but experienced rapid and sustained improvement when re-treated with dupilumab in OLE.