ATOPIC ECZEMA/DERMATITIS

EFFECT OF DUPILUMAB ON OBJECTIVE SCORAD (O-SCORAD) IN ADULTS WITH MODERATE-TO-SEVERE ATOPIC DERMATITIS: RESULTS FROM TWO IDENTICAL PHASE 3 TRIALS (LIBERTY AD SOLO 1 & SOLO 2)

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Introduction: Dupilumab (anti-IL-4Rα mAb) inhibits signaling of IL-4/IL-13, key drivers of type 2-mediated inflammation. Dupilumab is approved in the EU for treatment of moderate-to-severe AD in adults who are candidates for systemic therapy. The SCORAD (SCORing AD) index is used to assess AD extent and severity, including signs and symptoms. The o-SCORAD does not include symptoms.

Objective: To report the effect of dupilumab monotherapy on o-SCORAD in adults with moderate-to-severe AD (SOLO 1/SOLO 2: NCT02277743/NCT02277769).

Materials and Methods: 1,379 adults were randomized to dupilumab 300mg weekly (qw), every 2 weeks (q2w) or control (placebo) qw for 16 weeks (Wks). Outcomes included SCORAD: erythema, edema/papulation, oozing/crust, excoriation, lichenification, and dryness, and Body Surface Area (BSA). Improvements were assessed through least squares mean percent change from baseline using ANCOVA model with baseline measurement, region and baseline IGA stratum as covariates. Patients were censored after rescue treatment use, multiple imputation method was implemented for missing data.

Results: Treatment groups had balanced baseline characteristics. Dupilumab-treated patients showed improvements vs control by Wk1 in erythema, edema/papulation,

oozing/crust, excoriation, and lichenification ([qw/q2w vs control] erythema: –5.3%/–8.2% vs –1.2%; edema/papulation: –11.2%/–11.1% vs –1.2%; oozing/crust: –25.4%/–22.0% vs –2.2%; excoriation: –15.8%/–15.6% vs 2.8%; lichenification: –6.9%/–8.4% vs 1.0%), and by Wk4 in dryness ([qw/q2w vs control] –27.8%/–26.7% vs –6.7%). All improvements lasted through Wk16 ([qw/q2w vs control] erythema: –36.4%/–36.4% vs –16.6%, edema/papulation: –50.2%/–50.6% vs –23.1%, oozing/crust: –69.6%/–69.9% vs –37.7%, excoriation: –62.9%/–59.8% vs –22.8%, lichenification: –48.4%/–47.9% vs –21.4%, dryness: –44.5%/–40.5% vs –16.4%). BSA improved by Wk1 in both dupilumab arms, lasting through Wk16. Dupilumab had a favorable safety profile.

Conclusions: Dupilumab monotherapy for 16 weeks resulted in rapid, marked and sustained improvement in AD clinical signs and extent in adults with moderate-to-severe AD, as measured by o-SCORAD. BSA, erythema, edema/papulation, oozing/crust, excoriation, and lichenification improved by Wk1, and dryness by Wk4.