Dupilumab Provides Long-Term Efficacy for up to 4 Years in an Open-Label Extension Study of Adults With Moderate-to-Severe Atopic Dermatitis

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Background: Patients with chronic moderate-to-severe atopic dermatitis (AD) often have an inadequate response to topical therapies. Here, we present the long-term efficacy of dupilumab up to 4 years in adult patients with moderate-to-severe AD from an open-label extension (OLE) study (LIBERTY AD OLE, NCT01949311).

Methods: Adults (≥ 18 years) with moderate-to-severe AD who had participated in any dupilumab parent study (phase 1 to 3) were enrolled into the long-term, multicenter, OLE with an initial duration of 3 years and up to 5 years in certain countries. Initially, patients enrolled in the OLE were treated with 300 mg dupilumab weekly. In 2019, patients remaining in the study transitioned to dupilumab 300 mg every 2 weeks in alignment with the approved dupilumab dose regimen. Concomitant treatments for AD, including topical corticosteroid (TCSs) and topical calcineurin inhibitors (TCIs), were permitted. Data shown are for the overall study population.

Results: Of the 2677 patients who enrolled in the OLE, 2207 completed treatment up to Week 52, 1065 up to Week 100, 557 up to Week 148, 362 up to Week 172, and 352 up to Week 204. 240 patients had treatment duration > 204 weeks. Most withdrawals (810 [59.5%]) during the OLE study period were due to dupilumab approval and commercialization in the country in which the patient had enrolled, 114 (8.4%) patients withdrew due to adverse events and 58 (4.3%) withdrew due to lack of efficacy. At Week 204, 91% of patients achieved a 75% reduction in Eczema Area and Severity Index (EASI) from parent study baseline (PSBL), 76% of patients achieved a 90% reduction in EASI from PSBL, and 70.8% of patients achieved a ≥4-point reduction in the Peak Pruritus Numerical Rating Scale score from PSBL. A

total of 2273 (84.9%) patients reported treatment-emergent adverse events, and 99 (3.7%) patients discontinued treatment permanently due to reported adverse events. Dupilumab had an acceptable safety profile.

Conclusions: Long-term dupilumab treatment showed sustained efficacy with durable and progressive improvements in AD signs and symptoms in adults with moderate-to-severe AD up to 204 weeks. Dupilumab was generally well tolerated with an acceptable safety profile.

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