

Long-Term Efficacy and Safety of Dupilumab in Adolescents With Atopic Dermatitis: Results From an Open-Label Extension Trial (LIBERTY AD PED-OLE)

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Introduction: In the USA, dupilumab is approved for treatment of patients aged ≥ 12 years with moderate-to-severe atopic dermatitis (AD). Here, we report efficacy and safety data from 299 adolescent patients (≥ 12 to < 18 years) with moderate-to-severe AD who had previously participated in a phase 2a study of dupilumab (AD-1412, NCT02407756) and subsequently enrolled in an open-label extension (OLE) study (LIBERTY AD PED-OLE, NCT02612454).

Methods: In the phase 2a study, patients received a single weekly dose of dupilumab (2mg/kg or 4mg/kg) for 5 weeks. In the subsequent OLE study, patients continued weekly dupilumab (2mg/kg or 4mg/kg). We evaluated efficacy and safety data from the OLE study (n=299) with a data cutoff date of March 29, 2019.

Results: At Week 52, 46/106 (43.4%) of patients achieved an Investigator's Global Assessment (IGA) score of 0/1. The mean percent change (standard deviation) in Eczema Area and Severity Index (EASI) from the AD-1412 baseline to Week 52 of the OLE study (n=104) was -83.6% (23.3). 84/104 (80.8%) of patients achieved $\geq 75\%$ reduction from baseline in EASI (EASI-75) relative to their AD-1412 baseline. Treatment-emergent adverse events (TEAEs) were reported in 74.2% of patients; 18.1% of patients had a drug-related TEAE. The most common TEAEs were nasopharyngitis (21.1%), atopic dermatitis exacerbation (19.4%), upper respiratory tract infections (12.4%), headache (9.4%), and oropharyngeal pain (5.7%). Five patients reported serious TEAEs, of which none were treatment-drug related.

Conclusion: Data from this open-label extension trial of dupilumab support the long-term efficacy and safety of dupilumab in adolescents with AD.

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Disclosures

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