

Safety and Efficacy of Open-Label Dupilumab in Adult Patients With Moderate-to-Severe Atopic Dermatitis: An Analysis up to 3 Years (LIBERTY AD OLE)

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Introduction: Atopic dermatitis (AD) is a chronic inflammatory skin disease requiring long-term management. However, the continuous use of many treatments for AD is not recommended due to safety concerns. Dupilumab is a fully human monoclonal antibody that blocks the shared receptor component for interleukin (IL)-4 and IL-13, thus inhibiting signaling of both IL-4 and IL-13, key drivers of type 2 inflammation in multiple diseases. We report an analysis of dupilumab safety and efficacy of up to 3 years of treatment in patients with moderate-to-severe AD enrolled in a multicenter, open-label extension study (LIBERTY AD OLE, NCT01949311).

Methods: OLE enrolled patients who participated in dupilumab phase 1–3 trials (parent studies). Patients included in this analysis received subcutaneous dupilumab 300mg weekly for up to 148 weeks.

Results: A total of 2,678 patients were enrolled (60.2% male; mean age [standard deviation, SD] 39.2[13.42] years). At data cutoff (December 1, 2018), 82.4% patients completed to Week52 and 13.0% to Week148. 1,325 patients withdrew (mostly due to study termination by the sponsor after regulatory approval/commercial availability). Dupilumab compliance was high (98.15%). The incidence and exposure-adjusted rates of adverse events (AEs) here were similar or lower than with dupilumab 300mg weekly in the CHRONOS trial (NCT02260986). In OLE, 84.6% of patients had AEs, 9.2% severe AEs, 9.6% serious AEs (SAEs), 1.2% treatment-related SAEs, and 3.5% AEs leading to treatment discontinuation. Most common AEs were nasopharyngitis (28.1%), conjunctivitis (19.5%), AD exacerbation (16.4%), upper respiratory tract infection (13.1%), and headache (8.1%). At Week148, mean (SD) Eczema Area and Severity Index was 1.4(3.2) (32.8[13.2] at parent study baseline), and mean weekly average Peak Pruritus Numerical Rating Scale was 2.2(1.8) (7.1[1.9] at parent study baseline).

Conclusions: The long-term safety profile of dupilumab from this 3-year treatment study is consistent with previous findings in adults with moderate-to-severe AD treated with dupilumab, with sustained improvement in signs and symptoms of AD in patients who completed up to 3 years of treatment.

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Disclosures

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