Dupilumab Treatment for up to 3 Years Demonstrates Sustained Efficacy in Adult Patients With Moderate-to-Severe Atopic Dermatitis: Results From LIBERTY AD Adult OLE

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BACKGROUND
- Long-term use of systemic immunosuppressants such as cyclosporine for treatment of atopic dermatitis (AD) is not recommended due to safety concerns
- Previous dupilumab studies have demonstrated favorable safety and sustained efficacy in adult patients for up to 76 weeks.1

OBJECTIVES
- To report long-term (up to 3 years) efficacy of dupilumab in adult patients with moderate-to-severe AD who had previously participated in dupilumab studies (parent study) or had been screened for a phase 3 study, but could not be randomized because of randomization closure
- Eligible patients were ≥ 18 years of age who had previously participated in any dupilumab clinical trial, including early phase 1b trials

METHODS
- LIBERTY AD OLE is an ongoing, phase 3, multicenter study assessing the long-term safety and efficacy of repeat doses of dupilumab 300 mg weekly (qw) in adults with moderate-to-severe AD who had previously participated in dupilumab studies (parent study) or had been screened for a phase 3 study, but could not be randomized because of randomization closure
- Eligible patients were ≥ 18 years of age who had previously participated in any dupilumab clinical trial, including early phase 1b trials
- This analysis examined patients given dupilumab 300 mg qw for up to 148 weeks at data cutoff (December 1, 2018)
- The study was conducted in accordance with the provisions of Helsinki, the International Conference on Harmonization Good Clinical Practice guidelines, and applicable regulatory requirements; the protocol was reviewed and approved by institutional review boards/ethics committees at all study sites

Endpoints
- Primary endpoints were incidence and exposure-adjusted rates of adverse events (AEs)
- Secondary endpoints were incidence and exposure-adjusted rates of serious AEs (SAEs); proportion of patients with Investigator's Global Assessment (IGA) score 0–1 at Week 148; proportion of patients achieving ≥ 75% reduction in Eczema Area and Severity Index (EASI-75) from parent study baseline (PSBL) to Week 148

RESULTS
- 2,678 patients were enrolled, of which 2,677 were evaluated, 72.3% male, 72.3% white, mean age 59.2 years (Table 1)
- Baseline disease characteristics were consistent with previous clinical trials (Table 1)

OBJECTIVES
- To report long-term (up to 3 years) efficacy of dupilumab in adult patients with moderate-to-severe AD who had previously participated in the OLE study

RESULTS
- Efficacy analyses were performed using all observed data (intent-to-treat) with no imputation for missing values

Table 2. Safety overview: comparison between OLE and CHRONOS studies.

Table 3. The most common AEs: comparison between OLE and CHRONOS studies.

Table 4. Patient disposition, "TAF".

CONCLUSIONS
- Treatment with dupilumab for up to 3 years showed a favorable risk-benefit profile and sustained efficacy with no new safety signals associated with long-term exposure
- This safety profile in this long-term study is consistent with the known safety profile of dupilumab previously observed in controlled clinical trials in patients with moderate-to-severe AD

Acknowledgments

Disclosures


References


Blauvelt A, Beazley B, Patel N, Ruddy M, Staudinger H, Graham M, Shumel B. Dupilumab Treatment for up to 3 Years Demonstrates Sustained Efficacy in Adult Patients With Moderate-to-Severe Atopic Dermatitis: Results From LIBERTY AD Adult OLE. Presented at the 78th Annual Meeting of the American Academy of Dermatology (AAD 2020). Denver, CO; USA; March 20–24, 2020.