Efficacy and safety of dupilumab plus topical corticosteroids in patients with severe atopic dermatitis and prior history of dupilumab treatment: a post hoc subgroup analysis from ECZTRA 7 trial

**Introduction**

- **AD** is a chronic inflammatory disease, characterized by eczematous skin lesions and multiple symptoms, including pruritus, sleep disturbance, and depression.
- Dupilumab is a high-affinity, fully human, monoclonal antibody designed to specifically neutralize interleukin-4 (IL-4) and its closest homolog, interleukin-13 (IL-13), a key driver of the underlying inflammation in AD.
- The Phase 3 ECZTRA 7 trial (NCT03376357) met its primary endpoint of EASI-75 at Week 16, confirming dupilumab plus topical corticosteroids (TCS) is superior to placebo plus TCS in treating severe atopic dermatitis (AD) in patients not adequately controlled by, or with contraindications to, oral cyclosporine A.
- There can be inadequate disease control with currently available treatment options and many patients with severe AD continue to experience high disease burden.

**Objectives**

- To describe the efficacy and safety of dupilumab in a subgroup of ECZTRA 7 patients with prior history of dupilumab treatment.

**Methods**

- **ECZTRA 7** was a randomized, double-blind, multicenter, placebo-controlled Phase 3 trial.
- **Key inclusion criteria for ECZTRA 7**:
  - Adult patients with AD for ≥1 year with inadequate response to topical or oral systemic medication in the past year.
  - Disease not adequately controlled with, or with contraindications to, use of oral cyclosporine A.
  - AD involving ≥10% body surface area.
  - EASI ≥20 and IGA ≤3 at screening and at baseline.
  - Worst daily pruritus numeric rating scale (NRS) average score of ≥4 during the week prior to baseline.

**Figure 1. ECZTRA 7 trial design**

- **Table 1. Baseline demographics and clinical characteristics for randomized subjects in ECZTRA 7**
  - **Table 2. Binary efficacy endpoints in dupilumab-experienced patients**

**Results**

- **Patient characteristics**
  - Dupilumab-experienced (n=244) and placebo-naïve (n=233) cohorts had comparable baseline characteristics, except that median (interquartile range, IQR) age was 51.5 (43.0, 57.0) years for dupilumab-experienced patients and 33.0 (25.0, 45.0) years for placebo-naïve patients (Table 1).
  - Median (IQR) EASI and percentage of patients on oral medication at baseline of 35.3 (24.4, 39.4) and 51.0% among dupilumab-experienced patients and 28.7 (22.4, 39.5) and 49.0% among dupilumab-naïve patients, respectively.
  - Among dupilumab-experienced patients, baseline characteristics were similar between the TCS + as-needed (n=10) and placebo + as-needed (n=14) groups (Table 1):
    - 50% of patients in each of these two groups discontinued dupilumab due to either lack of efficacy or safety concerns.

**Table 3. Adverse events in dupilumab-experienced subjects through 26 weeks**

**Conclusions**

- This post hoc subgroup analysis indicates that dupilumab-experienced patients can benefit from tralokinumab + TCS as needed.
  - **Overall** adverse events in dupilumab-experienced patients treated with tralokinumab + TCS as needed were consistent with the pooled analysis of tralokinumab Phase 2 and 3 trials.
  - **Due to the small sample size,** further studies involving more patients are needed to confirm these findings.

**References**

- **Disclosures**

**Acknowledgements**

- **Table 2. Binary efficacy endpoints in dupilumab-experienced subjects**

- **Table 3. Adverse events in dupilumab-experienced subjects through 26 weeks**