Efficacy and Safety of Tralokinumab Plus Topical Corticosteroids in Patients with Severe Atopic Dermatitis and Prior History of Dupilumab Treatment: A Post Hoc Subgroup Analysis from ECZTRA 7 Trial

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Introduction

- AD is a chronic inflammatory disease characterized by eczematous skin lesions and multiple symptoms including pruritus, sleep disturbance, and depression
- Tralokinumab is a high-affinity, fully human, monomeric antibody designed to specifically neutralize interleukin-13, a key driver of the underlying inflammation in AD
- The Phase 3 ECZTRA 7 trial (NCT03761537) met its primary endpoint of EASI-75 at Week 16, confirming tralokinumab 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

Methods

- ECZTRA 7 was a randomized, double-blind, multicenter, placebo-controlled Phase 3 trial (Figure 1)

![Figure 1. ECZTRA 7 trial design.](image)

- Primary outcome was the EASI-75 endpoint
- Secondary outcomes included the DLQI, AD duration, age, IGA, and NRS
- Baseline characteristics were similar between the two groups

Results

- Patients with a prior history of dupilumab treatment were included in this subgroup analysis (Table 1)

![Table 1. Baseline demographics and clinical characteristics for randomized patients in ECZTRA 7](image)

- Tralokinumab response in dupilumab-experienced patients
  - Among dupilumab-experienced patients at Week 16, 100% (n = 6) of patients receiving tralokinumab + TCS achieved EASI-75 without the use of rescue therapy, compared to 50% (4/8) of those receiving placebo + TCS (difference [95% CI]: 50.0 [15.4, 84.6]; Table 2)
  - Numerically higher proportions of dupilumab-experienced patients receiving tralokinumab + TCS achieved IGA 0/1 (4/6, 66.7%) and EASI 0.5-3.0 (5/6, 83.3%, difference: 22.5 [0.9, 44.2]) at Week 26
  - Similarity, at Week 26, numerically higher proportions of dupilumab-experienced patients receiving tralokinumab + TCS achieved IGA 0/1 (4/6, 66.7%), EASI 0.5-3.0 (5/6, 83.3%), and NRS ≤4 (9/12, 75.0%) compared to placebo + TCS (3/6, 50.0%; IGA 0/1: 2/6, 33.3%; EASI 0.5-3.0: 3/6, 50.0%; NRS ≤4: 5/12, 41.7%)

![Table 2. Binary efficacy endpoints in dupilumab-experienced patients.](image)

- Safety
  - No serious adverse events occurred in either treatment group
- From a safety perspective, there were 2 patients who had previously discontinued dupilumab due to adverse events; no adjunctive treatments were not reported for either patient during 26 weeks of tralokinumab + TCS treatment

Conclusions

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

References


Disclosures

Jan Gutermuth reports honoraria as a consultant/advisory board member and/or an advisor/speaker for AbbVie, Genzyme, Leo Pharma, Lilly, Pfizer, Regenon, and Sanofi. Andrew E. Pink has acted as an advisor/speaker for AbbVie, Almirall, Janssen, Roche–Posay, Pfizer, Novartis, Pfizer, and Sanofi. Margrita Wom has served as a scientific advisor and/or clinical trial investigator and/or paid speaker for AbbVie, Allergan, Amgen, Novartis, and UCB.

Acknowledgments

The ECZTRA 7 clinical trial was sponsored by Leo Pharma A/S, Ballerup, Denmark. Originally presented at Revolutionizing Atopic Dermatitis (RAD), June 13, 2021.