Real-world safety and effectiveness of up to 12 months of tralokinumab treatment in adults with atopic dermatitis who discontinued dupilumab due to conjunctivitis

April W Armstrong[1], Cory Rubin[2], Silvia Ferruci[3], Pierre-Andre Becherel[4], Jose Juan Pereyra Rodriguez[5,6], Marni C Wiseman[7,8], Ahmed Ameen[9], Teodora Festini[10], Frank Vinther[10], Ida Vittrup[10], Diamant Thaçi[11]

[1]University of California Los Angeles, David Geffen School of Medicine, Division of Dermatology, Department of Medicine, Los Angeles, California, United States; [2]Michigan Dermatology Institute, Waterford, Michigan, United States [3]Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Dermatology Unit, Milan, Italy; [4]Dermatology and Clinical Immunology Unit, Antony Hospital, Antony, France; [5]Virgen del Rocio University Hospital, Department of Dermatology, Sevilla, Spain; [6]University of Sevilla, Department of Medicine, School of Medicine, Sevilla, Spain; [7]SKiNWISE DERMATOLOGY, Winnipeg, Manitoba, Canada; [8]Section of Dermatology, Department of Medicine, University of Manitoba, Manitoba, Canada; [9]NMC Specialty Hospital, Abu Dhabi, United Arab Emirates; [10]LEO Pharma A/S, Ballerup, Denmark; [11]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany.

Conclusions

- Among patients who discontinued dupilumab due to conjunctivitis, over 80% did not develop conjunctivitis related to tralokinumab therapy in a real-world setting. Conjunctivitis was primarily mild to moderate and did not lead to tralokinumab discontinuation
- Overall, tralokinumab treatment was associated with continued improvements in disease severity and quality of life over 12 months even in this population that had discontinued prior dupilumab therapy
- These findings suggest that tralokinumab is an effective and well-tolerated treatment for atopic dermatitis in patients who discontinue dupilumab treatment due to conjunctivitis

Background

- Atopic dermatitis (AD) is a chronic and burdensome disease which significantly impacts patients' quality of life
- During treatment with dupilumab, some patients discontinue therapy due to adverse events (AEs) including conjunctivitis
- Evidence suggests that tralokinumab is an effective and well-tolerated choice for patients with AD who have previously been treated with dupilumab

Objectives

- The TRACE study assesses the real-world effectiveness and safety of 12 months of tralokinumab treatment in adults with AD
- Here we report the safety and effectiveness of tralokinumab in patients who had discontinued dupilumab due to the AE conjunctivitis prior to initiating treatment with tralokinumab

Methods

- TRACE is a prospective, non-interventional, international, single-cohort study of adults with AD prescribed tralokinumab per national approved label at treating physician's discretion (**Figure 1**)
  - 824 patients were included in the full analysis set: 182 had previously received dupilumab before starting tralokinumab treatment; 39 had discontinued dupilumab due to the AE conjunctivitis
    - These 39 patients were predominantly male and White (**Table 1**)
- Safety outcomes included AEs; conjunctivitis was a predefined AE of special interest
- Effectiveness outcomes were assessed per routine clinical practice and included: Eczema Area and Severity Index (EASI); Dermatology Life Quality Index (DLQI); and Worst Weekly Itch numeric rating scale (Peak pruritus NRS)

Figure 1 TRACE study design

Inclusion criteria
- Adults (aged ≥18 years)
- Diagnosis of AD
- Tralokinumab-naïve (new users)

Exclusion criteria
- Participation in the active treatment phase of a clinical trial
- Previous enrollment in TRACE

Table 1 Baseline characteristics

Baseline demographics	Patients who discontinued dupilumab due to the AE conjunctivitis N=39
Mean age, years (SD)	**48.0** (17.90)
Male sex, n (%)	22 (**56.4%**)
Race	
White	27 (**69.2%**)
Asian	2 (**5.1%**)
Black or African American	2 (**5.1%**)
American Indian or Alaska Native	1 (**2.6%**)
Other	1 (**2.6%**)
Unknown*	6 (**15.4%**)

*Unknown includes unknown and not reported values.

Results

AEs in patients who had previously discontinued dupilumab due to conjunctivitis

- 39 (21.4%) of 182 dupilumab-experienced patients had discontinued dupilumab treatment due to the AE conjunctivitis (**Figure 2**)
- Tralokinumab was well-tolerated in these dupilumab-experienced patients, with low levels of reported AEs through 12 months (**Table 2**)
  - During tralokinumab therapy, 17 (43.6%) of the 39 patients reported one or more AE
  - Only 2 (5.1%) of the 39 patients discontinued tralokinumab due to an AE

Figure 2 Reported conjunctivitis with prior dupilumab treatment and tralokinumab treatment in TRACE

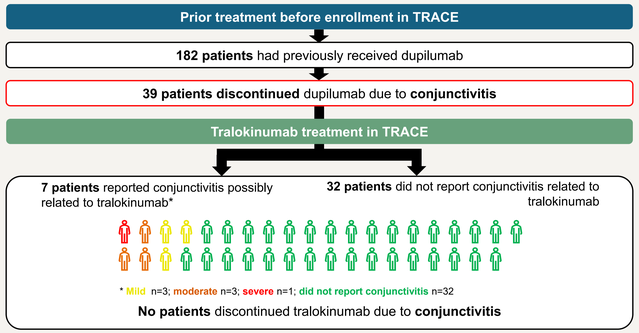
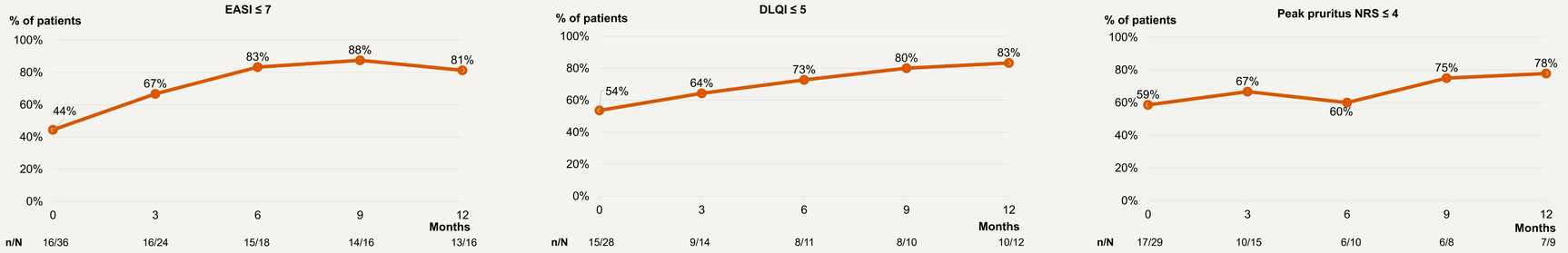


Figure 3 Disease improvements over time in patients who discontinued dupilumab due to AEs



Denominator for the proportions, N, is patients with at least one response assessment at the given visit.

- Conjunctivitis was the only AE by MedDRA preferred term reported by >1 of these 39 patients, occurring in 10 patients (25.6%)
- For 7 (17.9%) of these 39 patients, conjunctivitis was assessed by investigator as possibly related to tralokinumab
  - Of the 7 patients reporting conjunctivitis possibly related to tralokinumab, 6 patients reported mild or moderate conjunctivitis (**Figure 2**)
  - None of these 7 patients discontinued tralokinumab due to conjunctivitis

Table 2 Summary of adverse events, 52 weeks of treatment in the TRACE study

	Patients who discontinued dupilumab due to conjunctivitis N=39
Patients with at least 1 AE, n (%)	17 (43.6)
Patients with at least 1 SAE, n (%)	1 (2.6)
Patients with at least 1 AE related to tralokinumab*	11 (28.2)
Patients with at least 1 AE leading to discontinuation of treatment	2 (5.1)
Patients reporting conjunctivitis	10 (25.6)
Conjunctivitis related to tralokinumab, n (%)	7 (17.9)
Discontinued treatment due to conjunctivitis, n (%)	0 (0)

*Related AEs are defined as AEs assessed as possibly related by the investigator

Effectiveness in patients who discontinued dupilumab due to AEs

- Rapid and sustained improvements in disease severity and patient-reported outcomes were observed with up to 12 months of tralokinumab treatment
- The proportion of patients with mild disease increased rapidly during the trial
  - 81% of patients met EASI ≤ 7 by 12 months of tralokinumab treatment (**Figure 3**)
- The proportion of patients with low impact on their health-related quality of life increased rapidly
  - 83% of patients met DLQI ≤ 5 by 12 months of tralokinumab treatment (**Figure 3**)
- A steady increase was observed in the proportion of patients reporting low level itch
  - This is despite more than half of patients reporting PP-NRS ≤ 4 at baseline (**Figure 3**)

Abbreviations AD = atopic dermatitis, AE = adverse event, AESI = adverse event of special interest, DLQI = Dermatology Life Quality Index, EASI = Eczema Area and Severity Index, JAK = Janus kinase, n = number of subjects with observation, N = number of subjects in analysis set (or subset), NRS = numeric rating scale, SAE = serious adverse event, SD = standard deviation

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