Safety and adverse events of special interest in 825 adults with atopic dermatitis receiving up to 12 months of tralokinumab treatment in a real-world setting

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Objectives

- The TRACE study aims to assess the real-world safety and effectiveness of 12-months of tralokinumab treatment in patients with atopic dermatitis (AD)

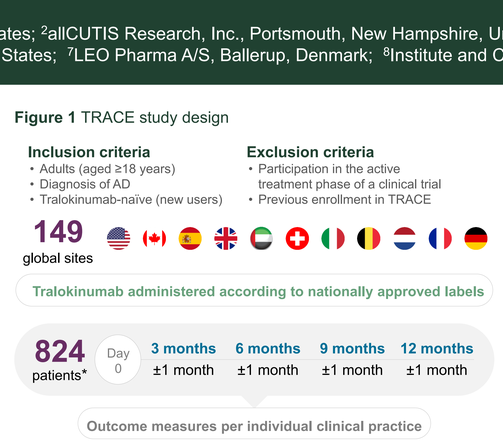
Background

- AD is a chronic and burdensome skin disease which significantly impacts patients' quality of life[1,2]
- For patients with moderate-to-severe AD, minimizing safety risks is a key treatment priority[1,2]
- Tralokinumab is a monoclonal antibody targeting interleukin-13, indicated for the treatment of moderate-to-severe AD, and has demonstrated efficacy and tolerability in Phase 3 clinical trials[3-5]
- Knowledge of the effectiveness and safety profile of tralokinumab in larger real-world cohorts is limited
- This study evaluates the safety, including predefined adverse events (AEs) of special interest (AESI), and effectiveness in patients with AD treated with tralokinumab for up to 12 months in a real-world setting

Methods

- TRACE is a prospective, non-interventional, international, single-cohort study of adults with AD who were prescribed tralokinumab per national approved label at treating physician's discretion (**Figure 1**)
  - 824 patients comprised the full analysis set and 825 comprised the safety analysis set
  - Patient baseline characteristics are shown in **Table 1**
- Safety outcomes included AEs and 2 predefined AESIs, namely conjunctivitis and major adverse cardiovascular events (MACE)
- Effectiveness outcomes measured per individual clinical practice included: Investigator Global Assessment (IGA), Eczema Area and Severity Index (EASI), and Scoring Atopic Dermatitis (SCORAD)
  - 2 composite clinical responder definitions were used:
    - Composite responder definition 1 (CR1): Patients achieving IGA 0/1 **or** EASI-75 **or** SCORAD < 10
    - Composite responder definition 2 (CR2): Patients achieving IGA 0/1 **or** EASI ≤ 7 **or** SCORAD < 10

Figure 1 TRACE study design



*835 patients were enrolled, of which 824 were included in the FAS and 825 in the SAF.

Table 1 Baseline characteristics

Baseline demographics	N=824
Mean age, years (SD)	44.1 (17.9)
Female sex, n (%)	392 (47.6)
Race	
White	624 (75.7)
Asian	44 (5.3)
Unknown*	71 (8.6)
Other†	85 (10.3)
Disease duration and prior systemic treatments	**N=824**
Duration of AD (n=814), mean (SD), years	18.8 (17.7)
Prior systemic treatment, n (%)	824 (100)
Systemic and biologic naïve	358 (43.4)
Systemic user but biologic naïve	261 (31.7)
Biologic user with one or more failures	173 (21.0)
Biologic user without failure	32 (3.9)

*Includes unknown, not available, and not reported values. †Includes American Indian/Alaska Native, Black/African American, Native Hawaiian/Pacific Islander, multiple races, and other.

Conclusions

- Tralokinumab treatment for up to 12 months was well-tolerated and effective in adults with AD in a real-world setting
- No new safety signals were identified with tralokinumab treatment in a real-world setting
- Conjunctivitis, a predefined AESI, was reported in less than 5% of patients and most conjunctivitis events were mild or moderate
- These findings reinforce the favorable benefit-risk profile of tralokinumab for moderate-to-severe AD

Results

Adverse events (AEs)

- 232 patients (28.1%) had at least 1 AE (**Table 2**)
- 132 patients (16.0%) had AEs that were assessed as possibly related to tralokinumab by the investigator
- Most AEs were non-serious and of mild or moderate severity (**Table 2**)
- The most frequently reported AEs (≥2% of patients) were:
  - 'Conjunctivitis' (4.4%)
  - 'Injection site reaction' (2.3%)

Serious adverse events (SAEs)

- SAEs were reported infrequently (27 events in 19 patients, 2.3%) (**Table 2**)
  - 3 deaths were reported, all assessed as not related to tralokinumab by the investigator
- No clustering of SAE types was observed
- All SAEs were assessed as not related to tralokinumab by the investigator, except for 1 event of 'eczema herpeticum' which was considered possibly related to tralokinumab
- Most SAEs had resolved or were resolving at the end of the study

Adverse events of special interest (AESIs)

- **Conjunctivitis:**
  - 40 events of 'conjunctivitis' were reported in 36 patients (4.4%) (**Table 2**)
    - None of the 40 events were serious
    - 37 of the events were mild or moderate in severity; 3 events were severe
    - 33 of the 40 events were assessed as possibly related to tralokinumab
    - In 4 patients (0.5%), conjunctivitis led to withdrawal of tralokinumab treatment
- **Major adverse cardiovascular events (MACE):**
  - MACE were reported in 5 patients with 5 events (**Table 2**):
    - 3 events of myocardial infarction;
    - 2 events of central nervous system hemorrhage and cerebrovascular conditions
  - None of these events were assessed as related to tralokinumab

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

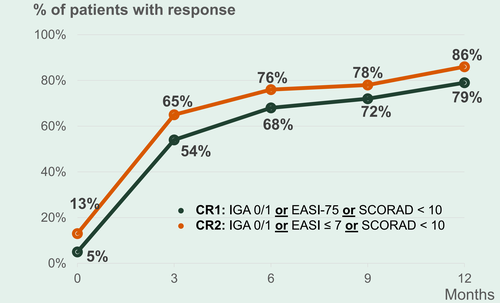
	N=825
Patients with at least 1 AE, n (%)	232 (28.1)
Patients with at least 1 SAE, n (%)	19 (2.3)
Death, n (%)[a]	3 (0.4)
Severity	
Mild, n (%)	158 (19.2)
Moderate, n (%)	98 (11.9)
Severe, n (%)	23 (2.8)
Related to tralokinumab[b]	132 (16.0)
AEs leading to treatment discontinuation	32 (3.9)
Most frequently reported preferred terms (in ≥2% of patients)	
Conjunctivitis, n (%)	36 (4.4)
Injection site reaction, n (%)	19 (2.3)
AESIs	
Conjunctivitis, n (%)	36 (4.4)
MACE, n (%)	5 (0.6)

[a]'Myocardial infarction', 'death', and 'pancreatic carcinoma' all assessed as not related to tralokinumab
[b]Related AEs are defined as AEs assessed as possibly related by the investigator

Effectiveness of tralokinumab treatment for 12 months

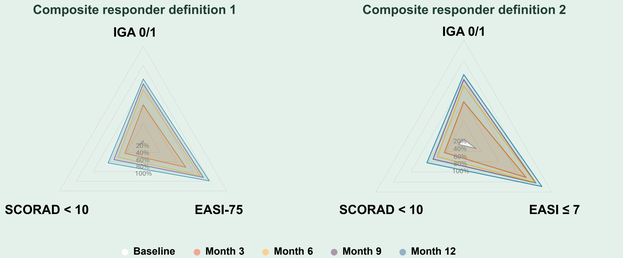
- Rapid improvements from baseline were observed after starting treatment with tralokinumab (**Figure 2**)
- Most patients had met a composite responder definition after 12-months tralokinumab therapy (**Figure 2**)
- AD severity decreased over 12 months tralokinumab, in all measures comprising composite responder definitions IGA, EASI and SCORAD (**Figure 3**)

Figure 2 Changes in composite response: baseline to month 12



CR1, n/N	42 / 794	352 / 656	369 / 539	315 / 438	326 / 412
CR2, n/N	108 / 818	430 / 659	409 / 540	342 / 440	356 / 415

Figure 3. Attainment in components of the composite response over 12-months



Denominator for the proportions, N, is patients with at least one response assessment at the given visit. Note that EASI-75 is 0 at baseline.

Abbreviations AD, atopic dermatitis; AE, adverse event; AESI, adverse event of special interest; SAE, serious adverse event; EASI, Eczema Area and Severity Index; EASI-75, at least 75% reduction in EASI score from baseline; FAS, full analysis set; IGA, Investigator's Global Assessment; n, number of subjects with observation; N, number of patients in analysis set (or subset); MACE, major adverse cardiovascular event; SAF, safety analysis set; SCORAD, Scoring Atopic Dermatitis, SD, standard deviation.

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References 1. Feldman SR, et al. *J Dermatolog Treat.* 2024;35(1):2345739; **2.** Ameen M, et al. *Acta Derm Venereol.* 2024;104:adv24339; **3.** Bieber T. Allergy. 2020;75(1):54-62; **4.**Wollenberg A, Blauvelt A, Guttan-Yassky E, et al. *Br J Dermatol.* 2021;184(3):437-449; **5.** Simpson EL, Blauvelt A, Silverberg JI, et al. *Am J Clin Dermatol.* 2024;25:139-148.

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