A global, observational, cohort study of patients with atopic dermatitis to evaluate tralokinumab real-world clinical use (TRACE): baseline characteristics from the first 100 patients in Germany

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Introduction

- Tralokinumab is a high-affinity, fully human IgG4 monoclonal antibody that specifically targets interleukin-13 (IL-13), a key driver in atopic dermatitis (AD) disease progression[1–3].
- Clinical trials have shown that tralokinumab is efficacious in patients with moderate-to-severe AD and has a favorable safety profile, including a low frequency of adverse events (AEs), such as conjunctivitis[1,4].
- Management of patients in routine clinical practice differs from those enrolled in clinical trials due to strict inclusion/exclusion criteria, and there is currently a lack of clinical data on tralokinumab use in the real-world setting.
- TRACE is an observational cohort study of patients with AD, which aims to better understand the effectiveness, safety, and clinical use of tralokinumab in the real-world setting.

Objective

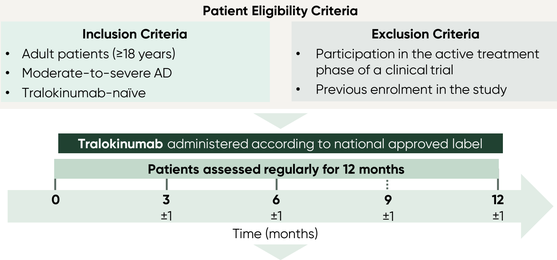
- To report the baseline characteristics from the first 100 patients enrolled into TRACE in Germany.

Materials and Methods

Study design

- TRACE is an observational, prospective, single-cohort study designed to assess changes in clinical signs and symptoms of patients with AD treated with tralokinumab in a real-world setting.
- Patients across up to 180 sites are planned to be enrolled in the study, which is taking place across multiple countries in Europe, North America, and the Middle East.
- Patients will be treated with tralokinumab according to national approved labels and will be assessed at scheduled timepoints over a 12-month period (**Figure 1**).

Figure 1. TRACE study design



Primary endpoints:

Change in clinical signs and symptoms of AD after 12 months of treatment

- IGA = 0 or 1
- 75% reduction in EASI from baseline
- SCORAD = 0–9.9

Secondary endpoints:

- Safety
- Baseline predictors of clinical response & characteristics of patients
- Co-medication use and discontinuation
- Real-world management of AD with tralokinumab
- Changes in QoL & PROs
- Use of AD-associated healthcare

AD, atopic dermatitis; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment
PRO, patient-reported outcome; QoL, quality of life; SCORAD, SCORing atopic dermatitis

Study design (cont'd)

- This non-interventional study follows the guidelines for Good Pharmacoepidemiology Practice and is conducted in accordance with the Declaration of Helsinki.
- Patient visits are scheduled according to local clinical practice and relevant data collected at every visit within 56 weeks after baseline.

Results

Baseline characteristics

- Of the first 100 patients initiated on tralokinumab in Germany, 58% were male and 93% were white; mean age was 44.7 (standard deviation [SD] 17.9) years and mean disease duration 26.9 (18.5) years (**Table 1**).
- Additional baseline characteristics by biologic-experienced and biologic-naïve treatment status are shown in **Table 1.**

Table 1. Baseline characteristics of the first 100 German patients in TRACE overall and by subgroups of interest

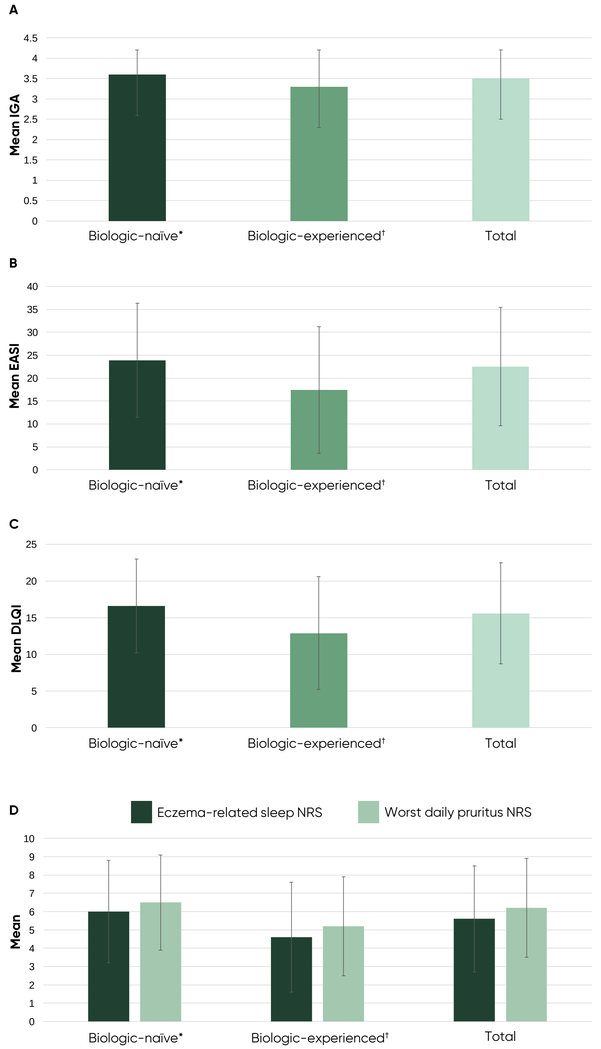
Baseline characteristic	Subgroup of interest			
	Biologic-naïve* (n=79)	Biologic-experienced† (n=19)	Missing (n=2)	Total (N=100)
Mean age, years (SD)	43.4 (17.8)	51.7 (17.5)	31.0 (1.4)	44.7 (17.9)
Gender, n (%)				
Female	32 (40.5)	10 (52.6)	0	42 (42.0)
Male	47 (59.5)	9 (47.4)	2 (100)	58 (58.0)
Race, n (%)				
Asian	1 (1.3)	1 (5.3)	0	2 (2.0)
Black	0	1 (5.3)	0	1 (1.0)
White	77 (97.5)	14 (73.7)	2 (100)	93 (93.0)
Missing	1 (1.3)	3 (15.8)	0	4 (4.0)
BMI, kg/m², n Mean (SD)	72 25.7 (5.5)	16 26.6 (4.0)	0 N/A	88 25.9 (5.3)
Disease duration, years, n Mean (SD)	78 24.6 (17.3)	19 36.3 (20.7)	0 N/A	97 26.9 (18.5)

*Defined as: systemic- and biologic-naïve, or systemic user but biologic-naïve
†Defined as: biologic user with ≥1 failure, or biologic user without failure
BMI, body mass index; n, number of patients in the analysis data set; N/A, not applicable; SD, standard deviation

Baseline disease severity and patient quality of life

- The majority of patients in whom disease severity was recorded had moderate-to-severe disease with a mean Investigator's Global Assessment (IGA) score of 3.5 (SD 0.7), and mean Eczema Area and Severity Index (EASI) of 22.5 (SD 12.9) (**Figures 2A and 2B**).
- In those for whom patient-reported outcomes were available, a substantial impact on quality of life was reported, as demonstrated by a mean Dermatology Life Quality Index (DLQI) of 15.6 (SD 6.9) (**Figure 2C**).
- Patients also reported a heavy symptomatic burden of disease, as demonstrated by mean eczema-related sleep Numerical Rating Scale (NRS) of 5.6 (SD 2.9) (**Figure 2D**) and mean worst daily pruritus NRS of 6.2 (SD 2.7) (**Figure 2D**).
- Baseline disease severity and patient quality-of-life parameters are also presented by previous biologic treatment (**Figure 2A–D**).

Figure 2. Baseline characteristics assessing disease severity and quality of life in patients enrolled into TRACE in Germany



Mean baseline readings of: **A**. IGA; **B**. EASI; **C**. DLQI; and **D**. Eczema-related sleep NRS and worst daily pruritus NRS of patients enrolled into TRACE in Germany.
*Defined as: systemic- and biologic-naïve, or systemic user but biologic-naïve
†Defined as: biologic user with ≥1 failure, or biologic user without failure
DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NRS, numeric rating scale

Previous treatments and reasons for switching

- Overall, 79 (79%) patients were biologic-naïve and 19 (19%) patients had previously been treated with dupilumab (data missing; n=2).
- The majority of biologic-experienced patients had experienced ≥1 treatment failure.
- Reasons for dupilumab discontinuation included lack or loss of efficacy and the occurrence of AEs (mainly conjunctivitis).

Baseline comorbidities

- Overall, 34% of patients had baseline comorbidities, the most common being allergies (20%) and asthma (17%) (**Table 2**).
  - Additional baseline comorbidities are summarized according to previous treatment.

Table 2. Baseline comorbidities by subgroups of interest

Baseline comorbidity	Subgroup of interest		
	Biologic-naïve* (n=79)	Biologic-experienced† (n=19)	Total (N=100)
Any comorbidity, n (%)	25 (31.6)	9 (47.4)	34 (34.0)
Allergy, n (%)	16 (20.3)	4 (21.1)	20 (20.0)
Arthropathy, n (%)	1 (1.3)	1 (5.3)	2 (2.0)
Asthma, n (%)	12 (15.2)	5 (26.3)	17 (17.0)
Cardiovascular disease, n (%)	4 (5.1)	1 (5.3)	5 (5.0)
Conjunctivitis, n (%)	6 (7.6)	1 (5.3)	7 (7.0)
Eye disease, n (%)	2 (2.5)	1 (5.3)	3 (3.0)
Psychiatric illness, n (%)	2 (2.5)	2 (10.5)	4 (4.0)

*Defined as: systemic- and biologic-naïve, or systemic user but biologic-naïve
†Defined as: biologic user with ≥1 failure, or biologic user without failure
n, number of patients in the analysis data set. Data were missing for 2 patients.

Conclusions

- Initial findings from the first 100 patients from TRACE in Germany showed that the majority (79%) of adult patients with moderate-to-severe AD treated with tralokinumab were biologic-naïve.
- These data indicate that tralokinumab is prescribed as first-line systemic treatment in the real world, in line with European Dermatology Forum guidelines[5].
- Of patients who switched from dupilumab, the main reasons for switching were lack or loss of effectiveness, and conjunctivitis, indicating a need for alternative biologic treatments such as tralokinumab.

References

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Disclosures

Diamant Thaçi is or has been a consultant, advisory board member, and/or investigator for AbbVie, Almirall, Amgen, Beiersdorf, Biogen, Boehringer Ingelheim, BMS, Eli Lilly, Galapagos, Galderma, Janssen-Cilag, LEO Pharma, MorphoSys, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc, Samsung, Sandoz, Sanofi, Sun Pharma and UCB.
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