Minimal disease activity with 12 months of tralokinumab treatment in adults with atopic dermatitis: Real-world data from the prospective, non-interventional, international TRACE study

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Conclusions

- After 12 months of real-world tralokinumab treatment, 91% of patients met at least one moderate target, while 78% met at least one optimal target, corresponding to minimal disease activity
- After 12 months of tralokinumab treatment, approximately three out of four patients met the criteria for both a moderate ClinRO and a moderate PRO target, with nearly half of patients reaching optimal targets for both types of measures
- These findings underscore the effectiveness of tralokinumab in enabling patients to attain meaningful improvements in both clinician- and patient-reported measures of disease activity in a real-world clinical setting

Objectives

- To examine moderate and optimal, corresponding to minimal disease activity (MDA), targets in patients with atopic dermatitis (AD) receiving up to 12 months of tralokinumab treatment in a real-world setting

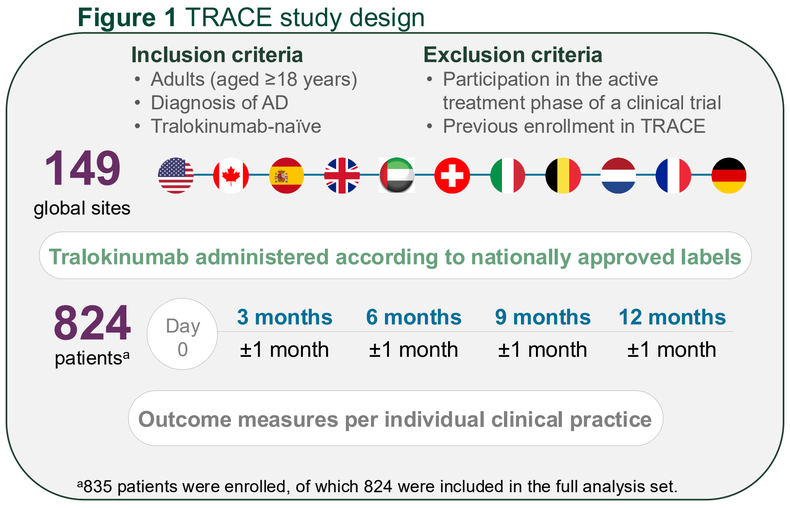
Background

- AD is a chronic and burdensome skin disease which significantly impacts patients' quality of life[1,2]
- Research indicates that many individuals with AD may not receive optimal treatment[3]
- The AHEAD recommendations set ambitious Clinician and Patient Reported Outcomes (ClinROs and PROs) targets for MDA in AD[4]
- Tralokinumab, a monoclonal antibody targeting interleukin-13, is indicated for the treatment of moderate-to-severe AD and has demonstrated efficacy and tolerability in phase 3 clinical trials[5-7]

Methods

- TRACE was a prospective, non-interventional, international, single-cohort study of 835 adults with AD who were prescribed tralokinumab according to the nationally approved label at the treating physician's discretion (**Figure 1**)
- ClinROs and PROs outcomes were assessed per individual clinical practice. Data are presented as observed
- **Moderate targets** included EASI-75, EASI≤7, SCORAD-50, SCORAD≤24, IGA≤2 and 50% improvement in BSA, ≥3-point reduction in sleep NRS, ≥4-point reduction in peak pruritus NRS, and ≥4-point reduction in DLQI
- **Optimal targets** included EASI-90, EASI≤3, SCORAD-75, SCORAD≤10, IGA 0/1 and BSA≤2%, peak pruritus NRS ≤1, sleep NRS ≤1, and DLQI≤1

Figure 1 TRACE study design



Baseline characteristics

- The mean age (SD) of participants was 44.1 (17.9) years; 52.4% of participants were male and 75.7% were White
- Baseline disease characteristics are reported in **Table 1**

Table 1 Baseline disease characteristics

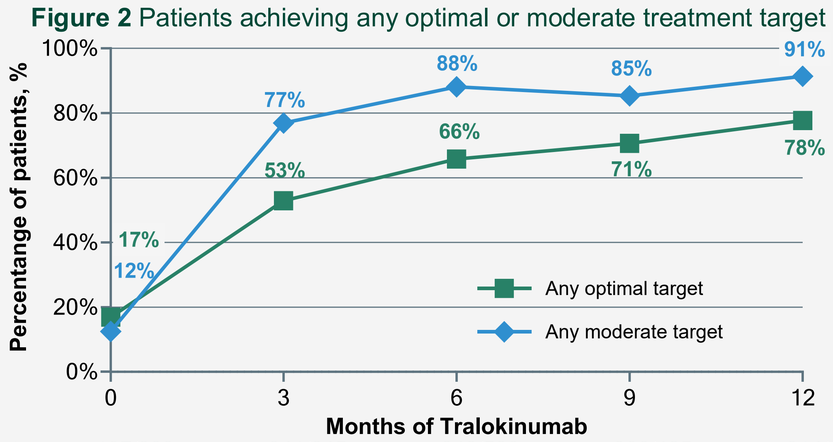
	All patients N=824
Mean duration of AD (n=814), years (SD)	18.8 (17.7)
BSA affected (n=694), mean (SD)	28.6 (21.9)
IGA (n=823)	
Severe, n (%)	281 (34.1)
Moderate, n (%)	414 (50.3)
Mild, n (%)	69 (8.4)
Almost clear, n (%)	13 (1.6)
Clear, n (%)	3 (0.4)
Not assessed, n (%)	43 (5.2)
EASI (n=640), mean (SD)	20.1 (11.1)
SCORAD (n=435), mean (SD)	47.1 (21.0)
DLQI (n=452), mean (SD)	12.8 (7.5)
Peak Pruritus NRS (n=490), mean (SD)	6.4 (2.5)
Sleep NRS (n=377), mean (SD)	5.1 (3.2)
Prior systemic treatment, n (%)	824 (100)
Systemic- and biologic-naïve	358 (43.4)
Systemic user but biologic-naïve	261 (31.7)
Biologic experienced with one or more treatment failures	173 (21.0)
Biologic experienced without treatment failure	32 (3.9)

Results

Minimal disease activity with 12 months of tralokinumab treatment in patients with AD

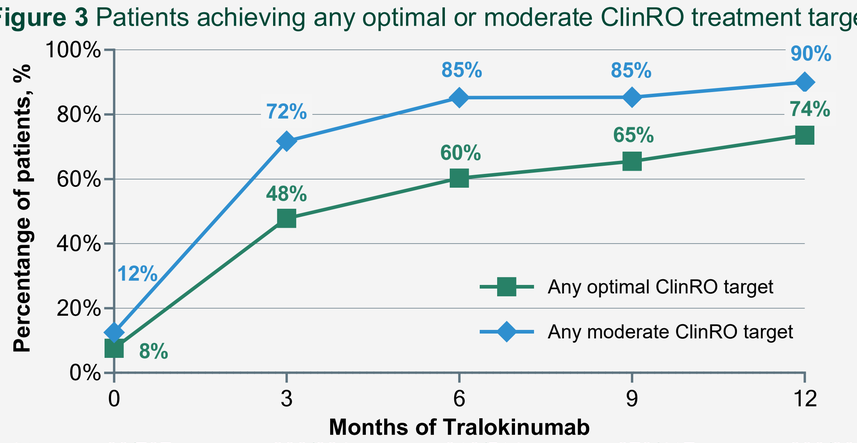
- At 12 months, the vast majority of patients met at least one optimal or moderate target, with the majority of patients meeting at least one MDA target by 3 months of treatment (**Figure 2**)
- The most commonly met moderate targets included EASI≤7 (88%) and IGA≤2 plus 50% improvement in BSA (84%). The most commonly reached optimal targets included EASI≤3 (74%) and Sleep NRS≤1 (57%)
- The percentage of patients meeting both ClinRO and PRO targets increased over time, with higher percentages of patients meeting ClinRO MDA targets (**Figures 3-4**)
- Approximately three quarters of patients had a combination of both a moderate ClinRO and a moderate PRO target, while just under half met both an optimal ClinRO and an optimal PRO target by 12 months of treatment (**Figure 5**)

Figure 2 Patients achieving any optimal or moderate treatment target



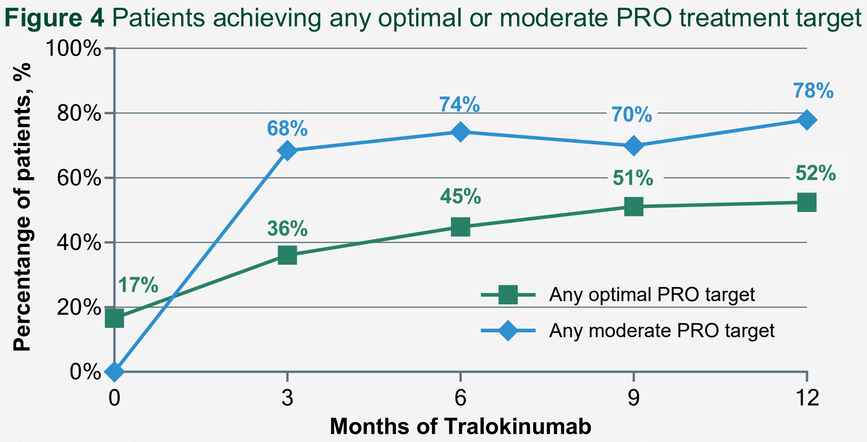
	0	3	6	9	12
optimal, n/N	137/809	341/645	342/520	300/425	314/404
moderate, n/N	92/738	488/635	451/512	355/416	363/397

Figure 3 Patients achieving any optimal or moderate ClinRO treatment target



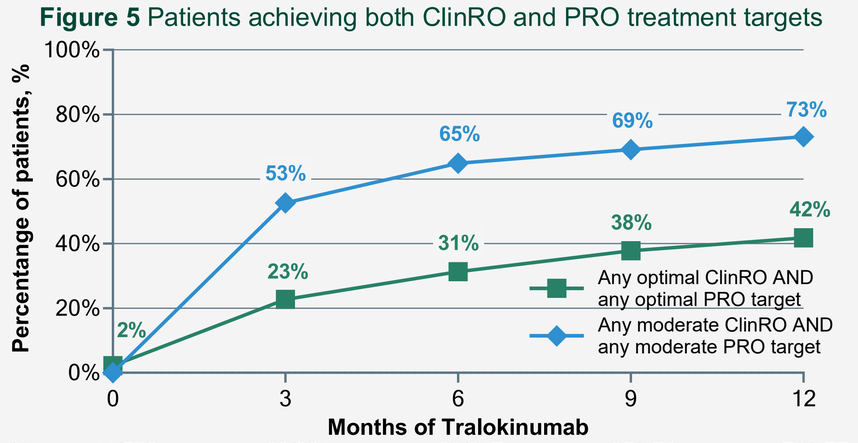
	0	3	6	9	12
optimal, n/N	60/787	298/624	310/514	273/417	290/394
moderate, n/N	92/738	441/615	430/505	349/409	349/388

Figure 4 Patients achieving any optimal or moderate PRO treatment target



	0	3	6	9	12
optimal, n/N	88/530	103/285	100/223	92/180	98/187
moderate, n/N	NA*	158/231	132/178	100/143	120/154

Figure 5 Patients achieving both ClinRO and PRO treatment targets



	0	3	6	9	12
optimal, n/N	11/508	60/264	68/217	65/172	74/177
moderate, n/N	NA*	111/211	111/171	94/136	106/145

*All moderate PRO treatment targets were defined as improvements from baseline and therefore do not have responders at 0 Months.

Abbreviations AD, atopic dermatitis; BSA, body surface area; ClinRO, Clinician Reported Outcome; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and SeverityIndex; EASI-75/90, at least 75%/90% reduction in EASI score from baseline; FAS, full analysis set; IGA, Investigator's Global Assessment; MDA, minimal disease activity; n, number of patients with indicated observation; N, number of patients with available data; NRS, numeric rating scale; PRO, Patient Reported Outcome; 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.** Pascal C, et al. *J Eur Acad Dermatol Venereol*. 2020;34(10):2339-2345. **4.** Silverberg JI, et al. *J Eur Acad Dermatol Venereol*. 2024;38(11):2139-48. **5.** Bieber T. *Allergy*. 2020;75(1):54-62. **6.**Wollenberg A, et al. *Br J Dermatol*. 2021;184(3):437-449. **7.** Simpson EL, et al. *Am J Clin Dermatol*. 2024;25:139-148.

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