Real-world effectiveness of 12 months' tralokinumab treatment in patients with skin of colour and atopic dermatitis: Final data from the prospective, non-interventional, international TRACE study

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Conclusions

- Patients with skin of colour (SoC) experienced substantially reduced atopic dermatitis (AD) severity and improved quality of life (QoL) over 12 months of tralokinumab treatment in a real-world setting
- Improvements were comparable to those in the overall TRACE study population

Objectives

- To evaluate the real-world effectiveness of up to 12 months of tralokinumab treatment in patients with AD and SoC in the TRACE study

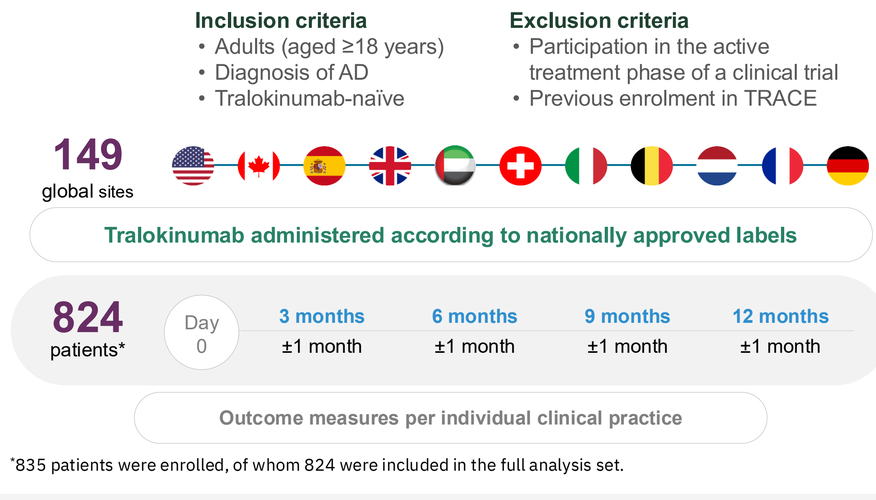
Background

- The clinical presentation of AD varies across different skin tones, posing unique challenges for diagnosis and management[1]
- People with SoC may have higher AD prevalence and severity, but remain underrepresented in dermatological research[1,2]
- Tralokinumab is an IL-13 targeting monoclonal antibody indicated for the treatment of moderate-to-severe AD, and has demonstrated efficacy and tolerability in phase 3 trials[3-6]

Methods

- TRACE is a prospective, non-interventional, international study of adults with AD prescribed tralokinumab per routine clinical practice
- **824 patients** comprised the full analysis set (FAS) (**Figure 1**)
- **131 patients (15.9%) had SoC** defined as Fitzpatrick skin type IV-VI (**Table 1**)

Figure 1 TRACE study design



*835 patients were enrolled, of whom 824 were included in the full analysis set.

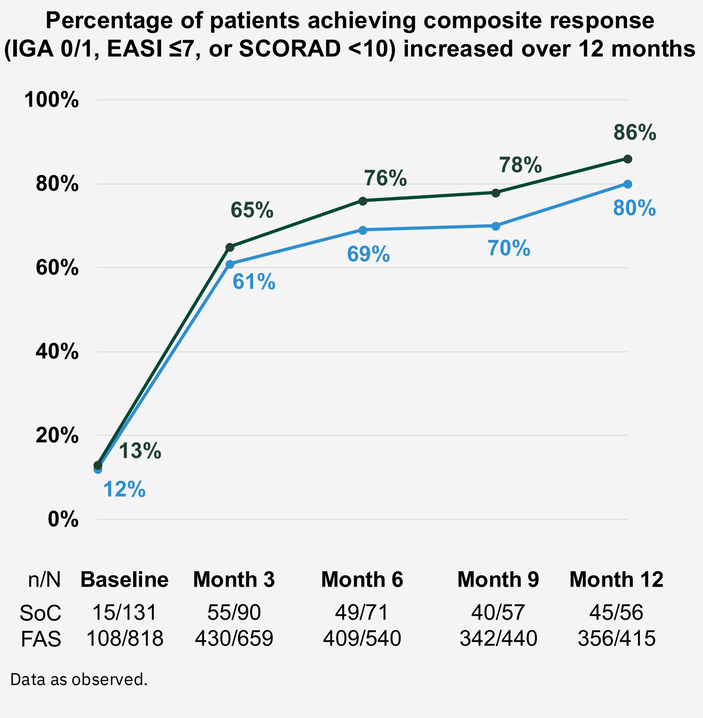
Table 1 Baseline characteristics

	Fitzpatrick IV-VI (N=131)	FAS (N=824)
Mean age, years (SD)	40.9 (15.2)	44.1 (17.9)
Male sex, n (%)	67 (51.1)	432 (52.4)
Mean duration of AD, years (SD)	*n=129* 16.1 (15.8)	*n=814* 18.8 (17.7)
IGA 4 (severe), n, (%)	46 (35.1)	281 (34.1)
Mean EASI, years (SD)	*n=80* 20.3 (12.0)	*n=640* 20.1 (11.1)
Mean DLQI, years (SD)	*n=73* 13.5 (7.7)	*n=452* 12.8 (7.5)
Mean Peak Pruritus-NRS, years (SD)	*n=88* 6.8 (2.3)	*n=490* 6.4 (2.5)

Results

Clinician-assessed improvements in tralokinumab-treated patients with AD and SoC consistent with FAS over 12 months

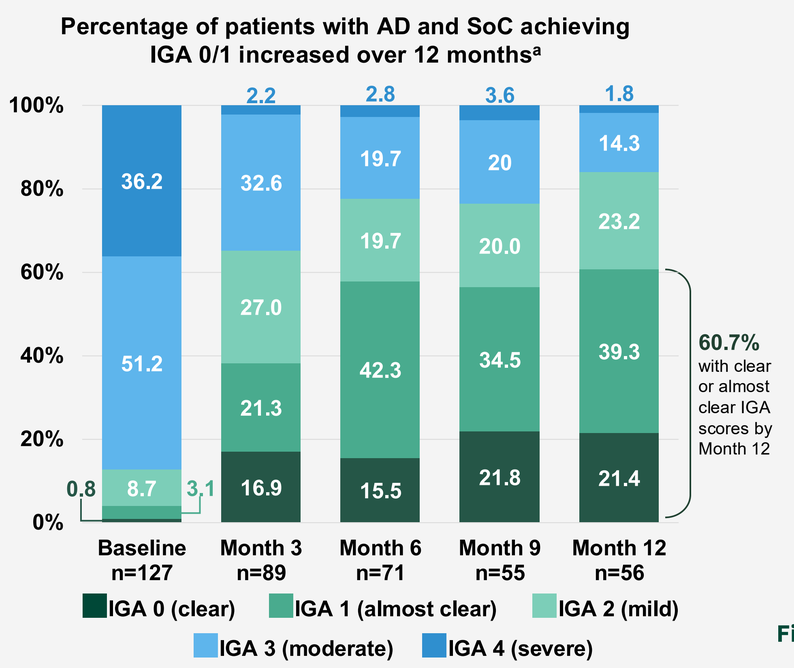
Figure 2 Composite response over 12 months



n/N	Baseline	Month 3	Month 6	Month 9	Month 12
SoC	15/131	55/90	49/71	40/57	45/56
FAS	108/818	430/659	409/540	342/440	356/415

Data as observed.

Figure 3 IGA response distribution over 12 months

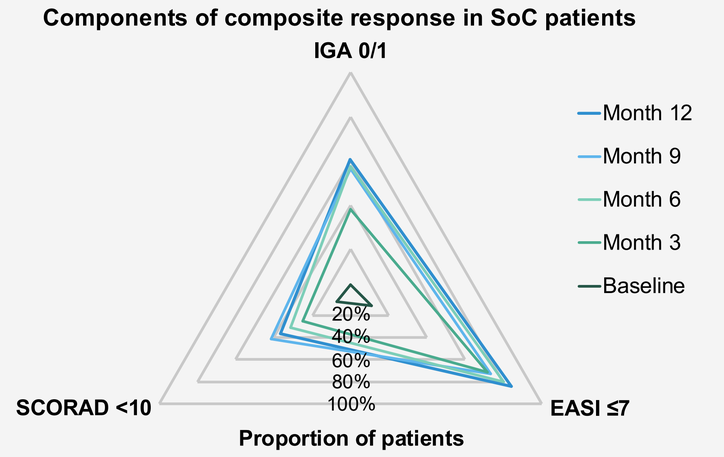


Data as observed. [a]Percentages based on patients with available observations at each visit.

Table 2 Investigator-assessed efficacy in patients with AD and SoC

	Baseline	Month 3	Month 6	Month 9	Month 12
IGA =4 Proportion (95% CI)	n=127 **36.2** (27.9-45.2)	n=89 **2.2** (0.3-7.9)	n=71 **2.8** (0.3-9.8)	n=55 **3.6** (0.4-12.5)	n=56 **1.8** (0.0-9.6)
≥2-point IGA improvement Proportion (95% CI)	-	n=85 **44.7** (33.9-55.9)	n=67 **59.7** (47.0-71.5)	n=53 **54.7** (40.4-68.4)	n=53 **64.2** (49.8-76.9)
SCORAD ≤24 Proportion (95% CI)	n=69 **15.9** (8.2-26.7)	n=44 **54.5** (38.8-69.6)	n=35 **68.6** (50.7-83.1)	n=29 **69.0** (49.2-84.7)	n=33 **81.8** (64.5-93.0)

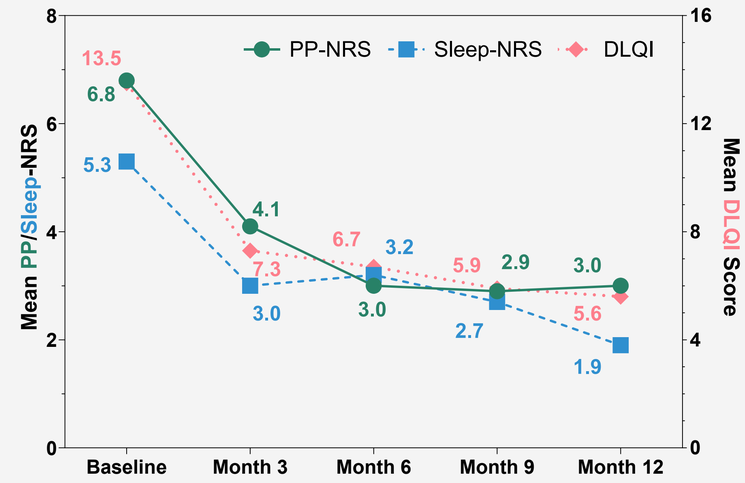
Figure 4 Improvements in IGA, EASI, and SCORAD over 12 months with tralokinumab



Patient-reported outcomes improved in tralokinumab-treated patients with AD and SoC over 12 months

- Rapid and substantial improvements in patient-reported itch, sleep and quality of life were observed over 12 months of tralokinumab treatment in patients with AD and SoC (**Figure 5**)

Figure 5 Patient-reported outcomes over 12 months



Sample size (n)					
PP-NRS:	88	40	33	21	24
Sleep-NRS:	55	26	18	13	15
DLQI:	73	39	30	21	23

Data as observed.

Abbreviations AD: atopic dermatitis; CI: confidence interval; DLQI: Dermatology Life Quality Index; EASI: Eczema Area and Severity Index; FAS: full analysis set; IGA: Investigator's Global Assessment; IL-13: interleukin-13; NRS: numeric rating scale; PP: peak pruritus; QoL: quality of life; SCORAD: SCORing Atopic Dermatitis; SD: standard deviation; SoC: skin of colour; TRACE: tralokinumab real world clinical use.

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References **1.** Davis CM, et al. *J Allergy Clin Immunol Pract*. 2023;11:1376-1383; **2.** Jacobs J, et al. *J Drugs Dermatol*. 2023;22:310-311; **3.** Bieber T. *Allergy*. 2020;75(1):54-62; **4.** Wollenberg A, et al. *Br J Dermatol*. 2021;184(3):437-449; **5.** Paller AS, et al. *JAMA Dermatol*. 2023;159(6):596-605. **6.** Simpson EL, et al. *Am J Clin Dermatol*. 2024;25:139-148.

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