Real-world effectiveness of tralokinumab in adults with atopic dermatitis: Interim data on improvements in patients with head and neck atopic dermatitis after up to 9 months of treatment in the TRACE study

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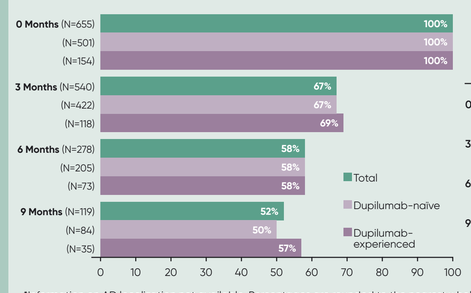
Objectives

- To evaluate the effectiveness of tralokinumab treatment on AD signs and symptoms in patients with head and neck (H&N) AD in an interim analysis of the noninterventional TRACE study

Results

- In patients with baseline H&N AD, the percentages who still reported H&N AD decreased through 9 months of tralokinumab **(Fig. 1)**

Figure 1. Decrease in percentages of patients with H&N AD.

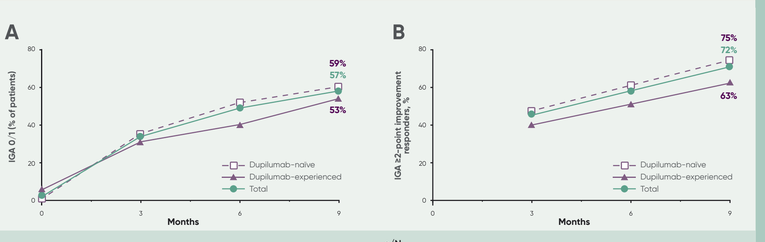


	% of patients with AD present on H&N	% of patients with clear skin on H&N	% of patients with unknown* on H&N AD
0 months	100 / 100 / **100**	0 / 0 / **0**	0 / 0 / **0**
3 months	67 / 67 / **69**	23 / 24 / **19**	10 / 9 / **13**
6 months	58 / 58 / **58**	25 / 25 / **26**	17 / 17 / **16**
9 months	52 / 50 / **57**	26 / 25 / **29**	22 / 25 / **14**

*Information on AD localization not available. Percentages are rounded to the nearest whole number.

- Percentages of patients with IGA 0/1 increased from 1% at baseline to 34% at 3 months and 57.4% at 9 months of tralokinumab **(Fig. 2A)**
- In patients with baseline IGA ≥2, the percentages achieving ≥2 improvement in IGA increased from 46% at 3 months to 72% at 9 months of tralokinumab **(Fig. 2B)**

Figure 2. Improvement in IGA-assessed disease severity.



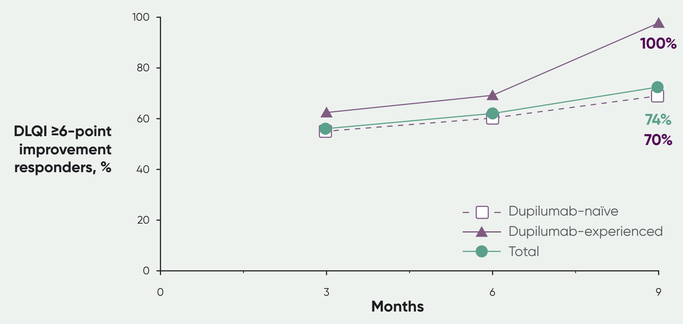
n/N			
Dupilumab-naïve	1/497	138/401	96/187	42/71
Dupilumab-experienced	8/153	34/111	25/63	16/30
Total	9/650	172/512	121/250	58/101

n/N			
Dupilumab-naïve	181/378	110/179	51/68
Dupilumab-experienced	39/96	30/58	17/27
Total	220/474	140/237	68/95

Percentages are rounded to the nearest whole number.

- In patients with baseline DLQI ≥6, the majority (57.9%) achieved ≥6 improvement in DLQI by 3 months of tralokinumab **(Fig. 3)**
- Percentages of patients with RECAP<6 increased from baseline to 9 months of tralokinumab treatment **(Fig. 4)**
- Mean PP-NRS and Sleep NRS improved from baseline to 9 months of tralokinumab treatment **(Fig. 5)**

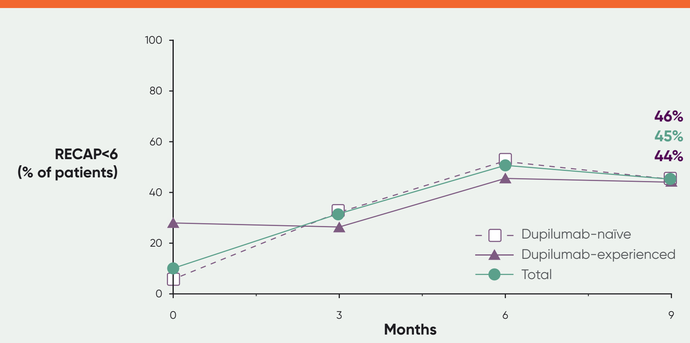
Figure 3. Clinically meaningful improvement in DLQI.



n/N			
Dupilumab-naïve	71/125	39/63	26/37
Dupilumab-experienced	13/20	10/14	6/6
Total	84/145	49/77	32/43

Percentages are rounded to the nearest whole number.

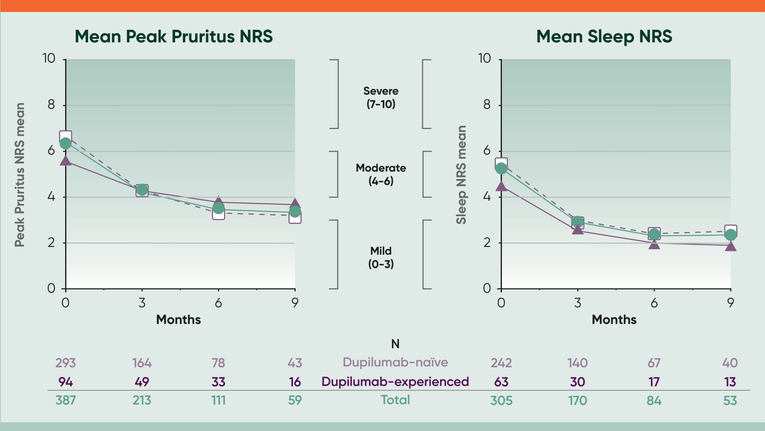
Figure 4. Improvement in patient-reported eczema control.



n/N				
Dupilumab-naïve	10/162	31/95	21/40	10/22
Dupilumab-experienced	11/39	5/19	6/13	4/9
Total	21/201	36/114	27/53	14/31

RECAP<6 identifies patients whose AD is considered completely controlled (RECAP score: 0-1) or mostly controlled (RECAP score: 2-5). Percentages are rounded to the nearest whole number.

Figure 5. Improvements in PP-NRS and Sleep NRS.



N				
Dupilumab-naïve	293	164	78	43
Dupilumab-experienced	94	49	33	16
Total	387	213	111	59

N			
Dupilumab-naïve	242	140	67	40
Dupilumab-experienced	63	30	17	13
Total	305	170	84	53

- Similar improvements were observed across endpoints in both dupilumabnaive and dupilumab-experienced patients

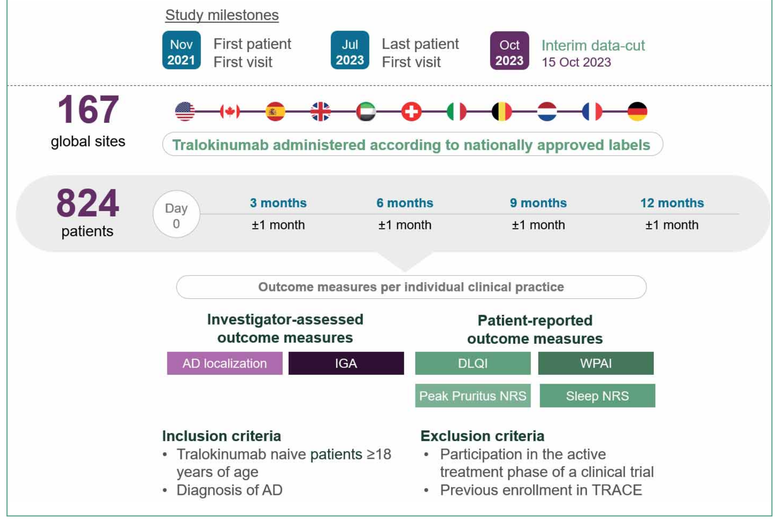
Background

- AD is an inflammatory skin disease that can affect multiple body areas[1]
- H&N region involvement is reported in 72% of patients with moderate-tosevere AD[1]
- AD with involvement of H&N, more than other body regions, is associated with social embarrassment, stigmatization, and negative impact on patients' quality of life and mental health[2]
- Tralokinumab is a high-affinity monoclonal antibody that specifically targets IL-13 and is indicated for treatment of moderate-to-severe AD[3,4]

Methods

- TRACE is a prospective, noninterventional, international, single-cohort study of adult patients with AD who were prescribed tralokinumab according to national approved labels **(Fig. 6)**
- Patients from 167 sites from 11 countries across Europe, North America, and the Middle East, were enrolled in TRACE between November 2021 and July 2023
- At data cutoff for this interim analysis (15 October 2023), not all patients had completed all visits
- This subanalysis included patients with AD involvement on the face, scalp, and/or neck at baseline
- Outcome measures collected included IGA, DLQI, RECAP, PP-NRS, and Sleep NRS, as per individual clinical practice
- Data presented as observed for baseline, 3-, 6-, and 9-month visits

Figure 6. TRACE study design.



Baseline and Disease Characteristics

- At baseline, 655 of 824 (80%) patients reported H&N AD **(Table 1)**
- Baseline demographics were similar, but dupilumab-naïve patients had higher baseline disease severity and greater impact on QoL vs dupilumab-experienced patients **(Table 1)**

Table 1. Baseline demographics and clinical characteristics.

	Dupilumab-naïve (N = 501)	Dupilumab-experienced (N = 154)	Total (N = 655)
Age (years), mean (SD)	41.1 (17.3)	45.2 (17.9)	42.1 (17.5)
Gender, n (%)			
Female	228 (45.5%)	80 (51.9%)	308 (47.0%)
Male	273 (54.5%)	74 (48.1%)	347 (53.0%)
Race, n (%)			
American Indian or Alaska Native	1 (0.2%)	1 (0.6%)	2 (0.3%)
Asian	29 (5.8%)	10 (6.5%)	39 (6.0%)
Black or African American	14 (2.8%)	7 (4.5%)	21 (3.2%)
Native Hawaiian or Pacific Islander	1 (0.2%)	1 (0.6%)	2 (0.3%)
White	387 (77.2%)	115 (74.7%)	502 (76.6%)
Multiple	2 (0.4%)	1 (0.6%)	3 (0.5%)
BMI (kg/m²), mean (SD)	26.5 (5.7)	27.2 (5.5)	26.7 (5.7)
Disease duration (years), mean (SD)	19.3 (17.0) *N = 489*	24.8 (19.9) *N = 153*	20.6 (17.8) *N = 642*
IGA 4 (severe disease), n (%)	193 (38.8%)	52 (34.0%)	245 (37.7%)
DLQI, mean (SD)	13.8 (7.7) *N = 287*	10.8 (7.2) *N = 78*	13.2 (7.7) *N = 365*
RECAP<6, n (%)	10 (6.2%) *N = 162*	11 (28.2%) *N = 39*	21 (10.4%) *N = 201*
Peak Pruritus NRS, mean (SD)	6.7 (2.4) *N = 293*	5.6 (2.9) *N = 94*	6.4 (2.6) *N = 387*
Sleep NRS, mean (SD)	5.4 (3.1) *N = 242*	4.4 (3.0) *N = 63*	5.2 (3.1) *N = 305*

Conclusions

- H&N involvement was common in patients with AD in previous reports[1], and present at baseline in 80% of patients in the real-world TRACE study
- Among patients with baseline H&N AD, tralokinumab treatment reduced the proportion with H&N involvement to 67% at 3 months and 52% at 9 months
- Tralokinumab improved AD severity and QoL at 3 months (IGA 0/1: 34%; DLQI ≥6 improvement: 58%), with further improvement up to 9 months (IGA 0/1: 57%; DLQI ≥6 improvement: 74%)

Abbreviations:

AD, atopic dermatitis; **BMI**, body mass index; **DLQI**, Dermatology Life Quality Index; **H&N**, head and neck; **IGA**, Investigator's Global Assessment; **IL**, interleukin; n, number of patients with the indicated metric; **N**, number of patients with available data; **NRS**, numeric rating scale; **PP-NRS**, Peak Pruritus NRS; **PRO**, patient-reported outcome; **QoL**, quality of life; **RECAP**, Recap for atopic eczema; **SD**, standard deviation; **TRACE**, Tralokinumab Real World Clinical Use.

References:

1. Silverberg JI, et al. J Am Acad Dermatol. 2023;89(3):519-528. **2.** Lio PA, et al. J Drugs Dermatol. 2020;19(10):943-948. **3.** Bieber T. Allergy. 2020;75(1):54-62. **4.** Wollenberg A, Blauvelt A, Guttman-Yassky E, et al. Br J Dermatol. 2021;184(3):437-449.

Disclosures:

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