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

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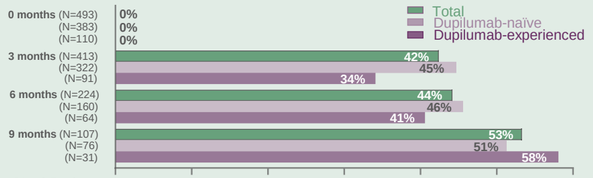
Objectives

- To evaluate the effectiveness of tralokinumab treatment on AD signs and symptoms in patients with hands and/or feet (H&F) AD in an interim analysis of the noninterventional TRACE study

Results

- Among patients who had H&F AD at baseline, 42.4% had clear skin on the H&F area at 3 months, which increased to 53.3% at 9 months of tralokinumab **(Fig. 1)**

Figure 1. Percentages of patients with clear skin on the H&F area

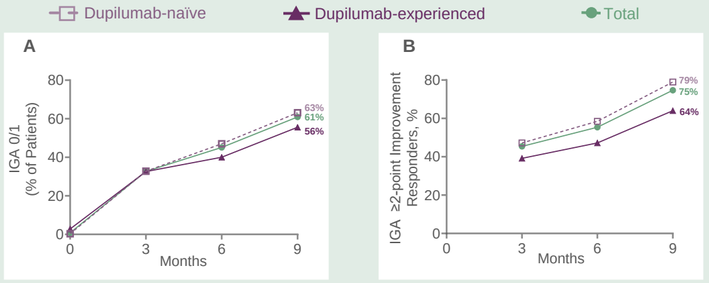


% of Patients	AD on H&F	Clear skin on H&F	Unknown* H&F AD
0 months	100 / 100 / 100	0 / 0 / 0	0 / 0 / 0
3 months	47 / 44 / 57	42 / 45 / 34	10 / 11 / 9
6 months	39 / 38 / 42	44 / 46 / 41	17 / 16 / 17
9 months	25 / 25 / 26	53 / 51 / 58	22 / 24 / 16

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

- Percentages of patients with IGA 0/1 increased from 0.8% at baseline to 32.7% at 3 months, and further increased to 60.9% at 9 months of tralokinumab **(Fig. 2A)**
- Among patients with baseline IGA ≥2, percentages achieving ≥2-point improvement in IGA increased from 45.4% at 3 months to 74.7% at 9 months **(Fig. 2B)**

Figure 2. Improvement in IGA-assessed disease severity

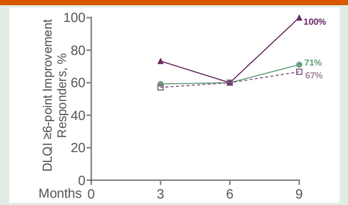


n/N				
1/379	99/302	70/149	41/65	Dupilumab-naïve
3/109	28/86	22/55	15/27	Dupilumab-experienced
4/488	127/388	92/204	56/92	Total

133/282	83/142	49/62	Dupilumab-naïve	215 128 63 40
31/79	25/53	16/25	Dupilumab-experienced	60 37 29 14
164/361	108/195	65/87	Total	275 165 92 54

- Among patients with baseline DLQI ≥6, percentages achieving ≥6-point reduction in DLQI increased from 59.2% at 3 months to 71.1% at 9 months of tralokinumab **(Fig. 3)**

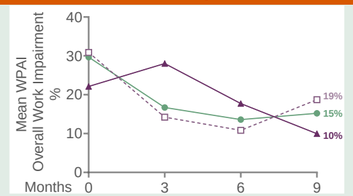
Figure 3. Improvement in QoL



n/N			
Dupilumab-naïve	60/105	33/55	22/33
Dupilumab-experienced	11/15	6/10	5/5
Total	71/120	39/65	27/38

- WPAI (percent overall work impairment) due to AD decreased from 29.7% at baseline to 16.7% at 3 months, and 15.2% at 9 months of tralokinumab **(Fig. 4)**

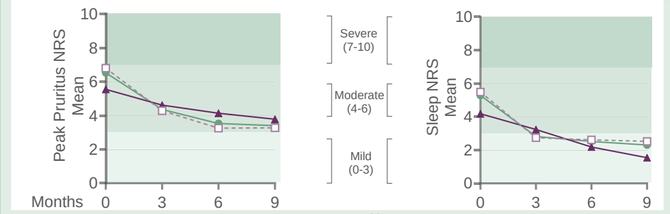
Figure 4. Improvement in patient-reported ability to work



N				
Dupilumab-naïve	75	41	12	9
Dupilumab-experienced	12	9	8	6
Total	87	50	20	15

- Mean peak pruritus and Sleep NRS scores improved by 3 months, with further improvement by 9 months of tralokinumab **(Fig. 5)**

Figure 5. Improvement in Pruritus and Sleep NRS



N				
Dupilumab-naïve	215	128	63	40
Dupilumab-experienced	60	37	29	14
Total	275	165	92	54

182	107	52	38	Dupilumab-naïve
33	21	16	11	Dupilumab-experienced
215	128	68	49	Total

Conclusions

- 42% of patients with baseline H&F AD reported clear skin on the H&F area after 3 months of tralokinumab, which increased to 53% at 9 months
  - Among dupilumab-experienced patients with baseline H&F involvement, 58% showed clear skin on the H&F area at 9 months of tralokinumab
- In this TRACE interim analysis, tralokinumab improved signs, symptoms, QoL, and work productivity in both dupilumab-naïve and dupilumab-experienced patients with H&F AD in a real-world setting.

Background

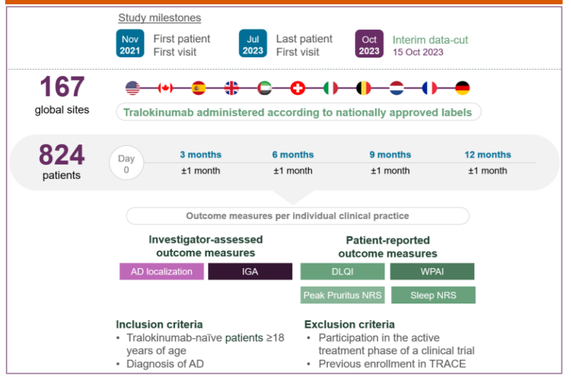
- AD is a chronic inflammatory skin disease that is associated with substantial disease burden[1]
- AD often affects the H&F, which are considered high-impact areas, due to significant negative impact on patients' quality of life and ability to work[2,3]
- Tralokinumab, a high-affinity monoclonal antibody that specifically targets IL-13, is indicated for the treatment of moderate-to-severe AD[4,5]

Methods

- TRACE is a prospective, noninterventional, 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
- This interim analysis, with a data cutoff of October 15, 2023, assessed patients with AD involvement on hands and/or feet at baseline
- Outcomes collected included AD localization, and overall AD measures; IGA, DLQI, WPAI, Peak Pruritus NRS, and/or Sleep NRS according to individual clinical practice
- Data presented as observed from baseline, 3-, 6-, and 9-month visits*

*Not all patients included in the analysis had completed all visits at the time of interim analysis data cutoff

Figure 6. TRACE study design



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Baseline and Disease Characteristics

- In patients with baseline H&F AD (59.8% of full analysis set), dupilumab-naïve patients reported slightly higher baseline disease severity and impact on QoL than dupilumab-experienced patients (**Table 1**)

Table 1. Baseline characteristics

	Dupilumab-naïve (N=383)	Dupilumab-experienced (N=110)	Total (N=493)
Mean age, years (SD)	41.6 (17.1)	48.1 (17.5)	43.0 (17.4)
Gender, n (%)			
Male	206 (53.8%)	51 (46.4%)	257 (52.1%)
Race, n (%)			
Asian	23 (6.0%)	7 (6.4%)	30 (6.1%)
Black/African American	7 (1.8%)	8 (7.3%)	15 (3.0%)
White	301 (78.6%)	79 (71.8%)	380 (77.1%)
Multiple	1 (0.3%)	1 (0.9%)	2 (0.4%)
Mean disease duration, years (SD)	19.7 (16.9) *N=375*	23.1 (20.9) *N=110*	20.5 (17.9) *N=485*
BMI (kg/m^2), mean (SD)	26.7 (5.4)	28.1 (6.2)	27.1 (5.6)
IGA 4 (severe), n (%)	144 (38.0%)	41 (37.6%)	185 (37.9%)
DLQI, Mean (SD)	14.3 (7.5) *N=217*	12.1 (7.8) *N=49*	13.9 (7.5) *N=266*
WPAI, Mean	30.9 *N=75*	22.1 *N=12*	29.7 *N=87*
Peak Pruritus NRS, Mean (SD)	6.8 (2.4) *N=215*	5.6 (2.6) *N=60*	6.5 (2.5) *N=275*
Sleep NRS, Mean (SD)	5.5 (3.1) *N=182*	4.2 (2.7) *N=33*	5.3 (3.0) *N=215*

Abbreviations

AD, atopic dermatitis; BMI, body mass index; DLQI, dermatology life quality index; H&F, hands and feet; 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; QoL, quality of life; RECAP, recap for atopic eczema; SD, standard deviation; WPAI, work productivity and activity impairment; TRACE, tralokinumab real world clinical use.

References

1. Weidinger S and Novak N. *Lancet*. 2016;387(10023):1109-1122. **2.** Silverberg JI, Simpson B, Abuabara K, et al., *J Am Acad Dermatol*, 2023; 89(3):519-528. **3.** Lee HJ, Ha SJ, Ahn WK, et al. *Pediatr Dermatol*, 2001;18(2):102-106. **4.** Bieber T. *Allergy*. 2020;75(1):54-62. **5.** Wollenberg A, Blauvelt A, Guttman-Yassky E, et al. *Br J Dermatol*. 2021;184(3):437-449.

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