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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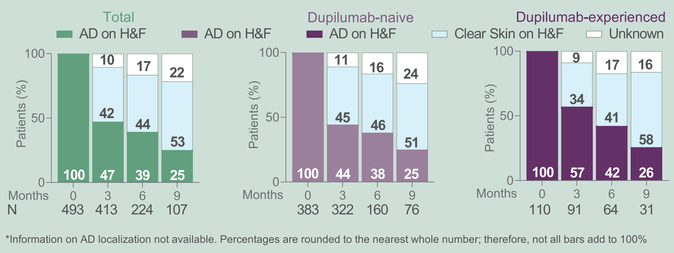
Objectives

- 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 no H&F AD at 3 months, which increased to 53.3% at 9 months of tralokinumab **(Fig. 1)**

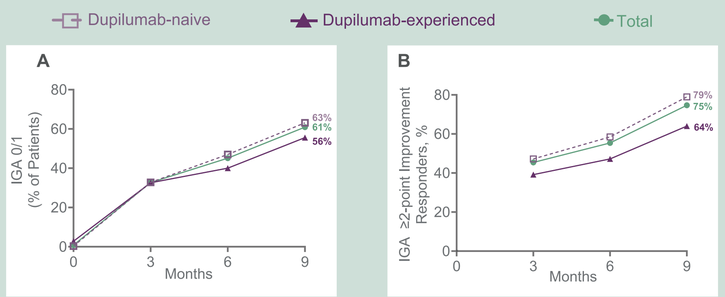
Figure 1. Percentages of patients with H&F AD



*Information on AD localization not available. Percentages are rounded to the nearest whole number; therefore, not all bars add to 100%

- 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)**

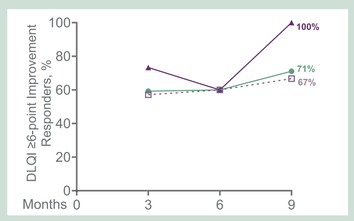
Figure 2. Improvement in IGA



n/N							
1/379	99/302	70/149	41/65	Dupilumab-naive	133/282	83/142	49/62
3/109	28/86	22/55	15/27	Dupilumab-experienced	31/79	25/53	16/25
4/488	127/388	92/204	56/92	Total	164/361	108/195	65/87

- 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)**

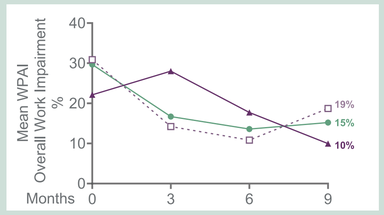
Figure 3. Clinically meaningful improvement in QoL



n/N			
Dupilumab-naive	99/302	70/149	41/65
Dupilumab-experienced	28/86	22/55	15/27
Total	127/388	92/204	56/92

- 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)**

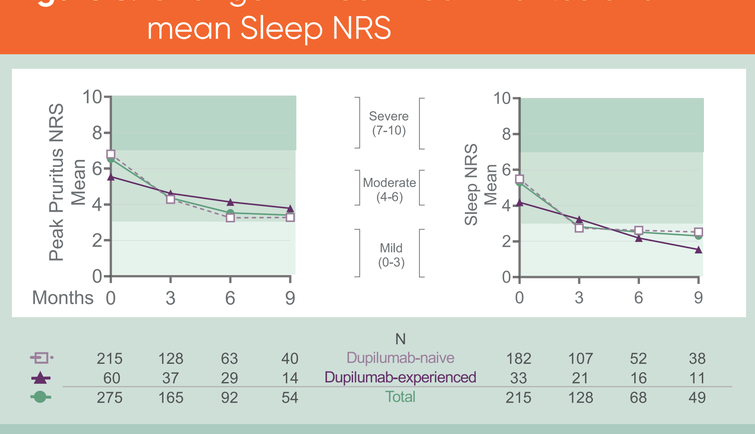
Figure 4. Decrease in work impairment by WPAI



N				
Dupilumab-naive	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. Change in mean Peak Pruritus and mean Sleep NRS



N								
215	128	63	40	Dupilumab-naive	182	107	52	38
60	37	29	14	Dupilumab-experienced	33	21	16	11
275	165	92	54	Total	215	128	68	49

Background

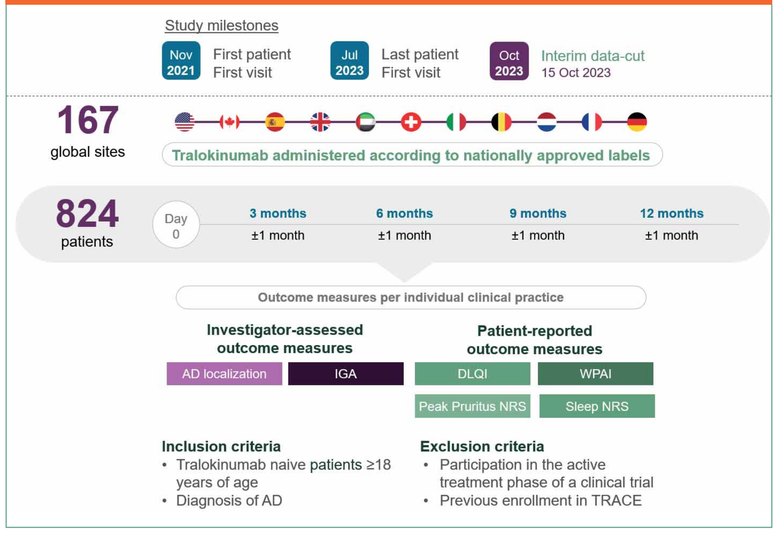
- AD is a chronic inflammatory skin disease that is associated with substantial disease burden[1]
- AD often affects the H&F, which are considered high-impact areas, due to significant negative impact on patients' quality of life and ability to work[2,3]
- Tralokinumab, a high-affinity monoclonal antibody 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 H&N AD patients included in the analysis had completed all visits at the time of interim analysis data cutoff

Figure 6. TRACE study design



Baseline and Disease Characteristics

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

Table 1. Baseline & Disease Characteristics

	Dupilumab-naive (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/m²), 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
RECAP<6, n (%)	7 (5.9%) n=118	4 (22.2%) n=18	11 (8.1%) n=136
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, Novak N. Lancet. 2016;387(10023):1109-1122. **2.** Silverberg, J.I., et al., J Am Acad Dermatol, 2023; 89(3):519-528. **3.** Lee, H.J., et al., Pediatr Dermatol, 2001;18(2):102-6.; 19(10):943-948. **4.** Bieber T. Allergy. 2020;75(1):54-62. **5.** Wollenberg A, et al. Br J Dermatol. 2021;184(3):437-449.

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Conclusions

- Treatment for 9 months with tralokinumab cleared H&F AD in more than 50% of patients
- Tralokinumab also improved signs, symptoms, QoL, and work productivity in patients with H&F AD in a real-world setting
- Similar improvements were observed across all endpoints in both dupilumab-naive and dupilumab-experienced patients with H&F AD