Real-world effectiveness of tralokinumab in adults with atopic dermatitis on the genitals: Interim data on improvements in physician-assessed disease severity and patient-reported outcomes in up to 3 months of treatment in the TRACE study

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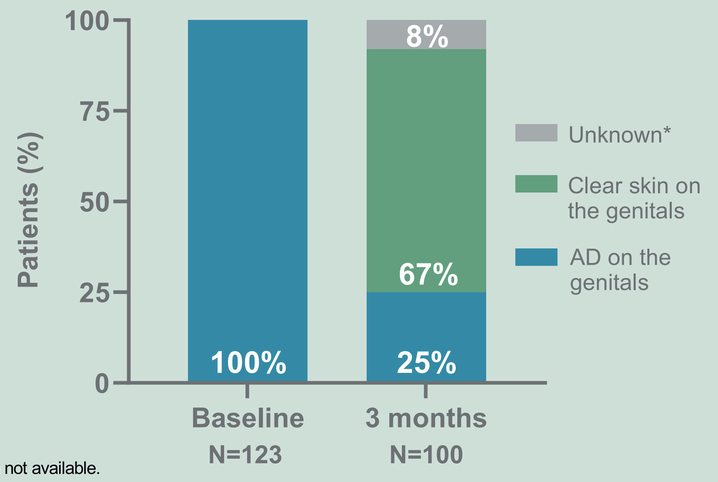
Objectives

- To evaluate changes in investigator-assessed disease severity and patient-reported outcomes in patients with AD on the genitals in an interim analysis of the noninterventional TRACE study

Results

- Among the patients who had AD on the genitals at baseline, the majority (67%) reported clear skin on the genitals by 3 months of tralokinumab treatment **(Fig. 1)**

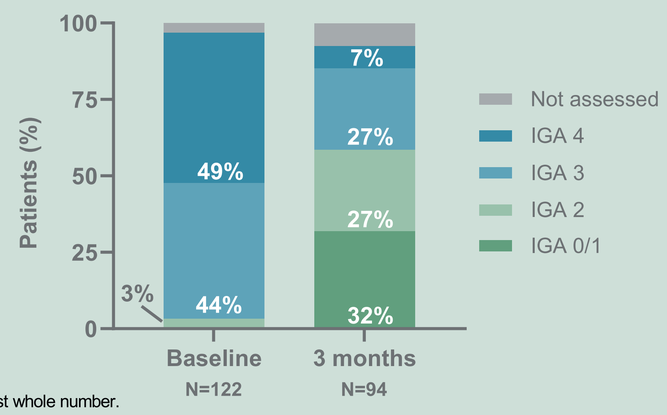
Figure 1. Proportion of patients with AD on the genitals at baseline and after 3 months of tralokinumab treatment



*Information on AD localization not available.

- The proportion of patients with IGA 0/1 (clear or almost clear disease) increased from 0% at baseline to 32% by 3 months of treatment, and the proportion of patients with IGA 4 (severe disease) decreased from 49% at baseline to 7% at 3 months **(Fig. 2)**
- Among patients with IGA ≥2 at baseline, approximately half of patients achieved an IGA reduction of ≥2 at 3 months **(Table 1)**

Figure 2. Improvement in IGA after 3 months of tralokinumab treatment



Percentages are rounded to the nearest whole number.

- Among patients with DLQI ≥6 at baseline, the majority achieved a DLQI reduction of ≥6 at 3 months **(Table 1)**
- Mean sleep NRS improved by approximately half from baseline to 3 months **(Table 1)**

Table 1. Improvement in additional endpoints from baseline to 3 months of tralokinumab treatment

Endpoint	Baseline	3 months
IGA reduction ≥2 n/N (%)	-	44/90 (48.9)
DLQI reduction of ≥6 n/N (%)	-	14/22 (63.6)
Sleep NRS Mean (lower error ; upper error)	N=50 6.16 (5.72 ; 6.60)	N=26 3.54 (2.90 ; 4.17)

Background

- AD is an inflammatory skin disease that can involve any part of the body, including the genital region[1,2]
- The presentation of AD on the genitals is often overlooked and underreported due to patients' reluctance to discuss this sensitive area with the clinician and the lack of routine examination of this region[1-3]
- Presence of AD in the genital area can have a significant negative impact on quality of life, including pain, sleep, mood, sexual function, and personal relationships[4,5]
- Tralokinumab, a high-affinity monoclonal antibody that specifically targets IL-13, is indicated for the treatment of moderate-to-severe AD[6,7]
- Recent case series have demonstrated successful use of tralokinumab in the treatment of AD on the genitals[1,2]

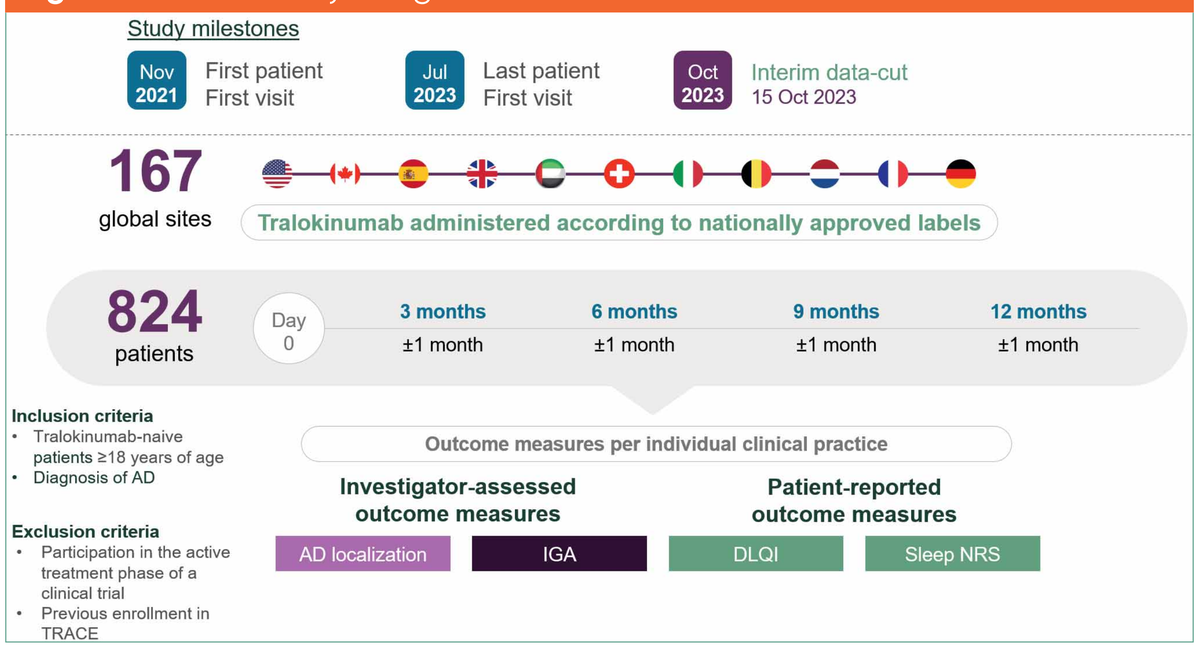
Conclusions

- An increased awareness of involvement of AD on the genitals and treatment options for this neglected area is essential
- Among adult patients with AD on the genitals at baseline, two-thirds reported clear skin on the genitals, with only 25% still reporting AD on the genitals, at 3 months of tralokinumab treatment in TRACE
- Patients with AD on the highly impactful genital region showed substantial improvements in AD severity and PROs with tralokinumab treatment in a real-world setting, including the proportion of patients with IGA ≤2 (clear-to-mild) increasing from 3% at baseline to 59% at 3 months

Methods

- TRACE is a prospective, non-interventional, international, single-cohort study of adult patients with AD who were prescribed tralokinumab according to national approved labels **(Fig. 3)**
- 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 subanalysis included patients with AD on the genitals at baseline with a data cutoff of October 15, 2023
- Outcome measures collected included: IGA, DLQI, and sleep NRS, as per individual clinical practice

Figure 3. TRACE study design



Baseline demographics

- Of the 824 patients in the total population, 14.9% had AD on the genitals at baseline **(Table 1)**
- Baseline demographics were similar between the total population and patients with AD on the genitals, though patients with AD on the genitals tended to have higher baseline disease severity, and a greater proportion were male, White, and in Europe

Table 2. Baseline characteristics

	Patients with genital AD (N=123)	Total population (N=824)
Mean age, years (SD)	42.2 (17.1)	44.1 (17.9)
Gender, male, n (%)	78 (63.4)	430 (52.2)
Race, n (%)		
White	100 (81.3)	624 (75.7)
Asian	5 (4.1)	44 (5.3)
Black or African American	3 (2.4)	37 (4.5)
Unknown	5 (4.1)	45 (5.5)
BMI (kg/m^2)	n=115	n=715
Mean (SD)	27.1 (6.0)	26.9 (5.8)
Country, n (%)		
Germany	57 (46.3)	226 (27.4)
Italy	20 (16.3)	149 (18.1)
United States	15 (12.2)	137 (16.6)
Canada	8 (6.5)	93 (11.3)
France	5 (4.1)	58 (7.0)
Switzerland	5 (4.1)	12 (1.5)
Belgium	4 (3.3)	24 (2.9)
Netherlands	4 (3.3)	18 (2.2)
Spain	3 (2.4)	40 (4.9)
Great Britain	1 (0.8)	29 (3.5)
United Arab Emirates	1 (0.8)	38 (4.6)
AD disease duration (years)	n=120	n=807
Mean (SD)	19.2 (16.6)	18.9 (17.8)
IGA, n (%)		
0 (Clear disease)	0 (0.0)	3 (0.4)
1 (Almost clear disease)	0 (0.0)	13 (1.6)
2 (Mild disease)	4 (3.3)	67 (8.3)
3 (Moderate disease)	54 (44.3)	401 (49.6)
4 (Severe disease)	60 (49.2)	275 (34.0)
DLQI	n=61	n=446
Mean (SD)	15.8 (7.6)	12.8 (7.5)
Sleep NRS	n=50	n=372
Mean (SD)	6.2 (3.1)	5.0 (3.2)

Abbreviations:

AD, atopic dermatitis; **BMI**, body mass index; **DLQI**, Dermatology Life Quality Index; **IGA**, Investigator's Global Assessment; **IL**, interleukin; **n**, number of patients who achieved the indicated metric; **N**, number of patients in indicated treatment set; **NRS**, numeric rating scale; **PRO**, patient-reported outcome; **SD**, standard deviation; **TRACE**, Tralokinumab Real World Clinical Use.

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