Real-world effectiveness and safety of 12 months of tralokinumab in patients with atopic dermatitis

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Supplementary Figures and Tables

Supplementary Table S1. Investigator-assessed effectiveness in adults receiving up to 12 months of tralokinumab therapy in the real-world TRACE study

Endpoints	Baseline N = 824	Month 3 N = 708	Month 6 N = 596	Month 9 N = 500	Month 12 N = 460
Composite responders,[a]					
n1/n2 (%)	42/794 (5.3)	352/656 (53.7)	369/539 (68.5)	315/438 (71.9)	326/412 (79.1)
(95% CI)	(3.8; 7.1)	(49.8; 57.5)	(64.4; 72.4)	(67.5; 76.1)	(74.9; 83.0)
Composite responders,[b]					
n1/n2 (%)	108/818 (13.2)	430/659 (65.3)	409/540 (75.7)	342/440 (77.7)	356/415 (85.8)
(95% CI)	(11.0; 15.7)	(61.5; 68.9)	(71.9; 79.3)	(73.5; 81.5)	(82.0; 89.0)
IGA 0/1 (clear/almost clear), n1/n2 (%)	16/780 (2.1)	245/631 (38.8)	288/521 (55.3)	257/424 (60.6)	263/397 (66.2)
IGA 0 (clear), n1/n2 (%)	3/823 (0.4)	86/673 (12.8)	95/547 (17.4)	99/446 (22.2)	136/417 (32.6)
IGA 1 (almost clear), n1/n2 (%)	13/823 (1.6)	159/673 (23.6)	193/547 (35.3)	158/446 (35.4)	127/417 (30.5)
IGA 2 (mild), n1/n2 (%)	69/823 (8.4)	212/673 (31.5)	137/547 (25.0)	105/446 (23.5)	89/417 (21.3)
IGA 3 (moderate), n1/n2 (%)	414/823 (50.3)	147/673 (21.8)	84/547 (15.4)	47/446 (10.5)	37/417 (8.9)
IGA 4 (severe), n1/n2 (%)	281/823 (34.1)	27/673 (4.0)	12/547 (2.2)	15/446 (3.4)	8/417 (1.9)
IGA missing/not assessed, n1/n2 (%)	44/823 (5.3)	77/673 (11.4)	75/547 (13.7)	73/446 (16.4)	63/417 (15.1)
IGA ≥2-point improvement,[c] n2		607	497	409	380
Percentage (95% CI)	-	46 (42; 50)	62 (57; 66)	66 (61; 71)	71 (66; 76)
EASI, n2	640	516	434	358	354
Mean (SD)	20.1 (11.1)	6.6 (7.5)	4.8 (6.6)	4.1 (6.0)	2.9 (4.8)
EASI-50, n2	-	493	407	341	333

Percentage (95% CI)		75 (71; 79)	83 (79; 86)	86 (82; 90)	89 (85; 92)
EASI-75, n2	-	493	407	341	333
Percentage (95% CI)		51 (46; 55)	68 (63; 72)	72 (67; 77)	79 (74; 83)
EASI-90, n2	-	493	407	341	333
Percentage (95% CI)		27 (23; 79)	43 (38; 48)	48 (42; 53)	57 (52; 63)
EASI ≤7, n2	640	516	434	358	354
Percentage (95% CI)	14 (11; 17)	71 (66; 74)	81 (77; 84)	82 (78; 86)	89 (85; 92)
SCORAD, n2	435	324	260	226	209
Mean (SD)	47.1 (21.0)	24.8 (17.73)	20.3 (15.9)	19.1 (16.9)	15.4 (16.0)
SCORAD <10, n2	435	324	260	226	209
Percentage (95% CI)	6 (4; 9)	22 (17; 26)	30 (24; 36)	35 (29; 42)	42 (35; 49)
SCORAD ≤24, n2	435	324	260	226	209
Percentage (95% CI)	16 (13; 20)	52 (47; 58)	63 (57; 69)	67 (61; 73)	75 (69; 81)
BSA, n2	694	561	463	373	355
Mean (SD)	28.6 (21.9)	12.0 (16.3)	8.2 (12.4)	7.4 (13.2)	5.0 (8.8)

[a]Composite responders are defined as patients with IGA 0/1, EASI-75, or SCORAD <10. [b]Composite responders are defined as patients with IGA 0/1, EASI ≤7, or SCORAD <10. [c]Among patients with baseline IGA ≥2.

824 patients were included in the full analysis set. Percentages are calculated using n2 as the denominator.

AD, atopic dermatitis; BSA, body surface area; CI, confidence interval; EASI, eczema area and severity index; EASI-50/75/90, 50%/75%/90% reduction from baseline in EASI; IGA, investigator's global assessment; N, number of patients in the analysis set; n1, patients achieving the endpoint; n2, number of patients with available data; SCORAD, scoring atopic dermatitis; SD, standard deviation.

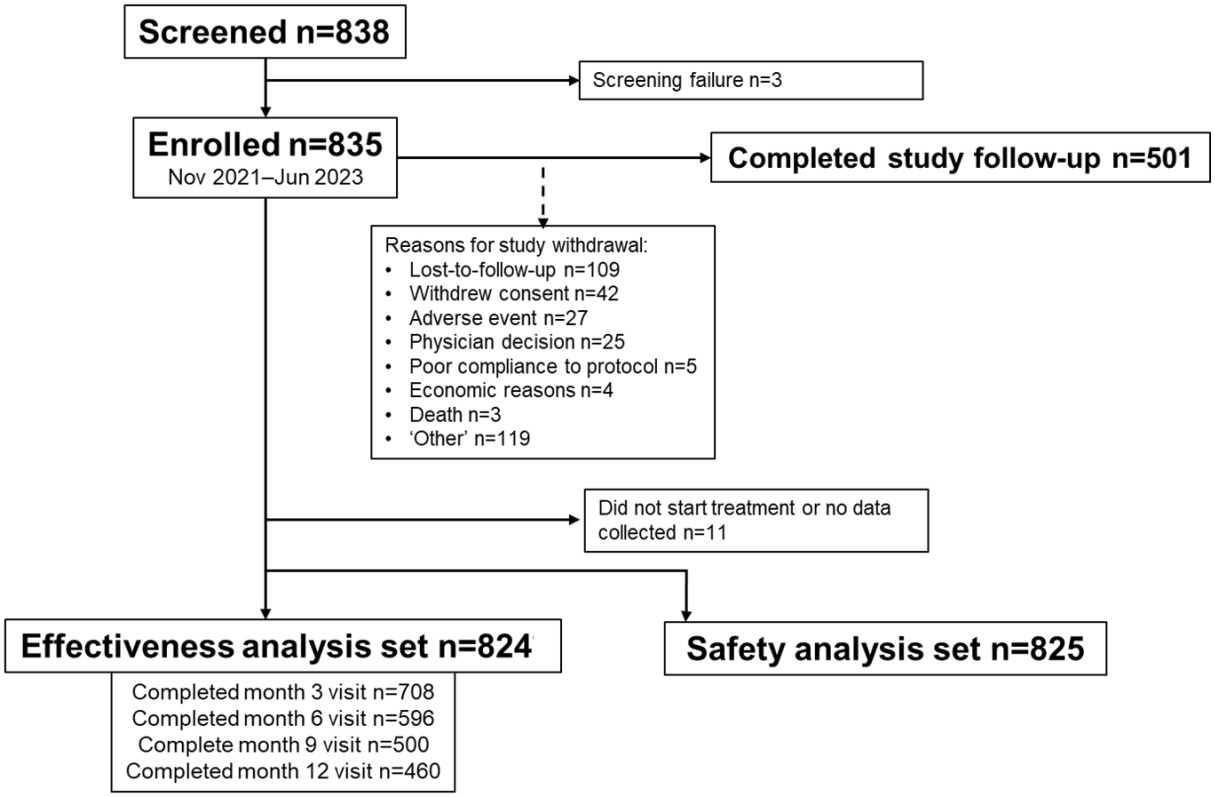
Supplementary Table S2. PROs and WPAI-GH assessments during 12 months of tralokinumab treatment

Assessment	Baseline (N = 824)	Month 3 (N = 708)	Month 6 (N = 596)	Month 9 (N = 500)	Month 12 (N = 460)
DLQI, n	452	243	195	161	170
Mean (SD)	12.8 (7.5)	7.1 (6.0)	5.8 (5.5)	5.5 (6.0)	5.0 (5.0)
DLQI ≤5, n	452	243	195	161	170
Proportion (95% CI)	0.20 (0.16; 0.24)	0.47 (0.40; 0.53)	0.62 (0.54; 0.68)	0.67 (0.59; 0.74)	0.67 (0.59; 0.74)
PP-NRS, n	490	258	206	164	171
Mean (SD)	6.4 (2.5)	4.3 (2.7)	3.4 (2.6)	3.3 (2.6)	3.3 (2.5)
PP-NRS ≤4, n	490	258	206	164	171
Proportion (95% CI)	0.22 (0.19; 0.26)	0.52 (0.45; 0.58)	0.68 (0.62; 0.75)	0.70 (0.62; 0.77)	0.71 (0.63; 0.77)
Sleep-NRS, n	377	202	150	130	130
Mean (SD)	5.1 (3.2)	2.8 (2.8)	2.4 (2.7)	2.3 (2.6)	2.3 (2.8)
ADCT, n	280	166	123	105	115
Mean (SD)	13.9 (6.4)	7.9 (5.8)	7.2 (5.5)	6.6 (5.6)	6.4 (5.4)
RECAP, n	239	145	103	82	93
Mean (SD)	16.5 (7.1)	10.0 (6.9)	8.9 (6.7)	8.2 (6.7)	7.7 (6.7)
WPAI-GH, n					
Mean (SD)					
Health-related work time missed	152	86	74	57	66
	8.7 (22.3)	4.2 (10.9)	7.1 (21.6)	3.0 (10.4)	2.1 (9.0)
Health-related work time impairment	150	88	70	56	66
	32.0 (26.6)	20.5 (26.8)	18.4 (23.7)	21.3 (26.3)	17.1 (22.8)
Overall health-related work impairment	146	86	70	56	65
	29.4 (24.5)	18.7 (24.3)	16.8 (20.3)	20.1 (25.2)	16.1 (21.7)
Health-related activity impairment	248	153	113	91	99
	43.7 (30.8)	25.5 (27.3)	23.3 (27.3)	21.5 (24.9)	22.5 (28.6)

ADCT, Atopic Dermatitis Control Tool; DLQI, Dermatology Quality of Life Index; PP-NRS, peak pruritus numeric rating scale; PRO, patient-reported outcome; RECAP, Recap of Atopic Eczema; SD, standard deviation; Sleep-NRS, Sleep numeric rating scale; WPAI-GH, Work Productivity and Activity Impairment-General Health.

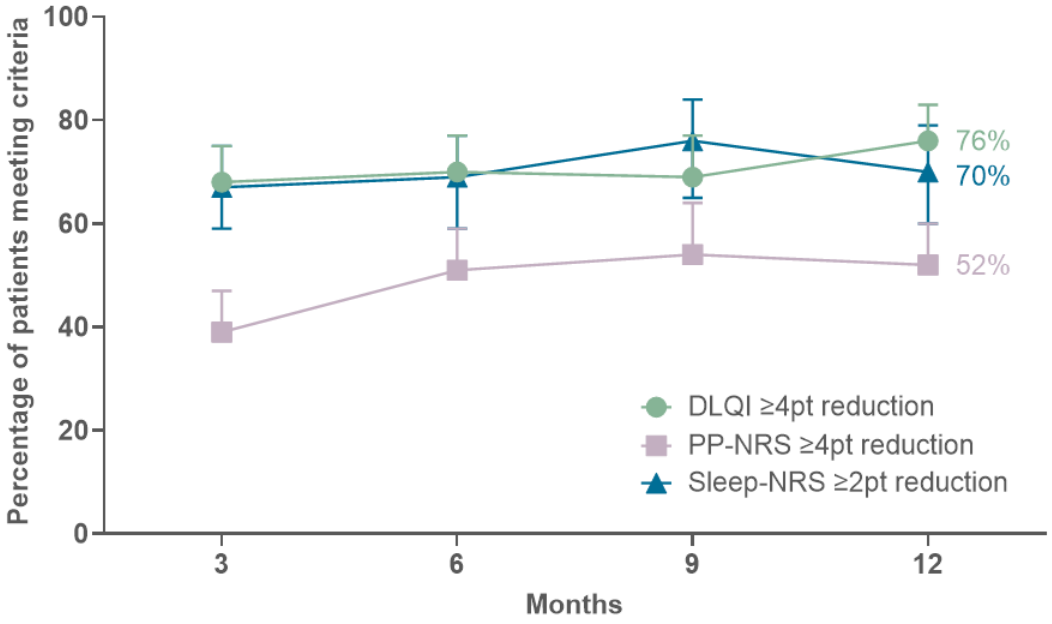
Supplementary Figure S1. Patient disposition.

The safety analysis set included all patients who received at least one dose of tralokinumab and included 825 patients, one of which received one dose of tralokinumab but was a screening failure and therefore excluded from the effectiveness analysis set.



Supplementary Figure S2. Percentages of patients meeting minimal clinically important differences in patient-reported outcomes for DLQI, PP-NRS, and sleep-NRS up to 12 months of tralokinumab treatment in the real-world TRACE study.

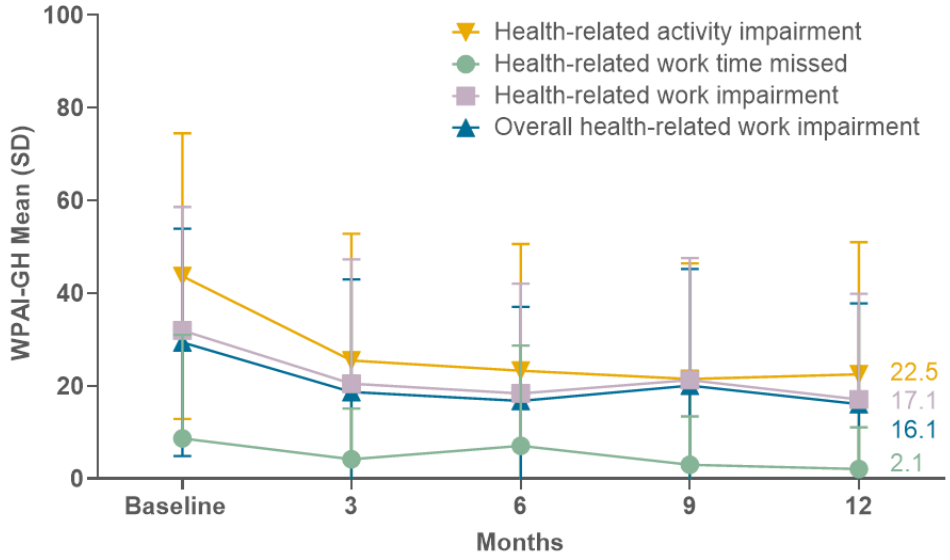
Reductions are shown among patients with a score of at least 4 (DLQI and PP-NRS) or 2 (Sleep-NRS) at baseline. The number of patients with data available for each timepoint per parameter is shown under each respective timepoint. Error bars represent 95% CI. CI, confidence interval; DLQI, dermatology life quality index; NRS, numeric rating scale, PP, peak pruritus.



DLQI	193	152	120	137
PP-NRS	198	152	114	128
Sleep-NRS	143	105	86	94

Supplementary Figure S3. Work Productivity and Activity Impairment-General Health (WPAI-GH) scoring over up to 12 months of tralokinumab treatment.

Number of patients with available data per metric per timepoint are displayed below the figure. Error bars represent SD. PRO, patient-reported outcome; SD, standard deviation; WPAI-GH, work productivity and activity impairment-general health.



Health-related activity impairment	248	153	113	91	99
Health-related work time missed[a]	152	86	74	57	66
Health-related work impairment[b]	150	88	70	56	66
Overall health-related work impairment	146	86	70	56	65

[a]Work time missed refers to absenteeism. [b]Work impairment refers to presenteeism.