Reduced dosing frequency with tralokinumab provides sustained improvements in symptoms and quality of life up to 1 year in adults with moderate-to-severe AD

April Armstrong,[1] Leon Kircik,[2] Ketty Peris,[3] Melinda Gooderham,[4] Sebastien Barbarot,[5] Aleksandra Lesiak,[6] Rie von Eyben,[7] Niels Højsager Bennike,[7] Ann-Marie Tindberg,[7] Margitta Worm[8]

[1]University of California Los Angeles, Los Angeles, CA, USA; [2]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [3]Università Cattolica del Sacro Cuore, Rome, Italy; [4]SKiN Centre for Dermatology, Peterborough, ON, Canada; [5]University Hospital of Nantes, Nantes, France; [6]Medical University of Lodz, Lodz, Poland; [7]LEO Pharma A/S, Ballerup, Denmark; [8]Charité Universitätsmedizin Berlin, Berlin, Germany

Conclusion

- Tralokinumab Q4W provided sustained improvements in itch, sleep, and QoL in patients with moderate-to-severe AD who had achieved clear or almost clear skin with initial Q2W dosing

Objectives

- To assess the long-term efficacy of reduced dosing frequency with tralokinumab on symptoms and QoL in adults with moderate-to-severe AD in the subgroup of patients who achieved clear/almost clear skin with initial Q2W dosing

Background

- Approved tralokinumab maintenance dosing regimens for treatment of moderate-to-severe AD include 300 mg Q2W and Q4W[1,2]
- Clinicians may consider tralokinumab Q4W for patients who reach clear or almost clear skin with initial Q2W dosing
- Previous analyses have mainly focused on the maintenance of clinician-measured skin clearance outcomes with reduced dosing frequency
  - In the pooled ECZTRA 1 (NCT03131648) and ECZTRA 2 (NCT03160885) trials, 42.4% of IGA 0/1 Week 16 responders maintained response at Week 52 with reduced dosing frequency[3]
- Patient-reported outcomes are becoming increasingly valued alongside skin clearance to assess treatment efficacy and disease burden, thus providing important information for guiding treatment decisions[4]
  - In the TCS-combination study ECZTRA 3 (NCT03363854), sustained improvements in DLQI were shown for the Q2W and Q4W arms at Week 32[5]

Methods

- This post hoc analysis utilized pooled data from the ECZTRA 1 & ECZTRA 2 phase 3 trials[6]
- Patient-reported outcomes were assessed in the subgroup of adults who achieved clear or almost clear skin (IGA 0/1) at Week 16 with initial tralokinumab 300 mg Q2W monotherapy and were subsequently re-randomized to continue tralokinumab 300 mg Q2W (N = 93) or reduce dosing frequency to Q4W (N = 85) for an additional 36-week maintenance period (**Table 1**)
- Outcomes were analyzed as observed and included DLQI (0-30 scale), worst daily pruritus NRS (0-10 scale), and eczema-related sleep interference NRS (0-10 scale)
  - Supplementary analyses using LOCF for missing data were conducted

Table 1 ECZTRA 1 & 2 demographics and disease characteristics

	Week 16 responders re-randomized to tralokinumab 300 mg Q2W (N = 93)	Week 16 responders re-randomized to tralokinumab 300 mg Q4W (N = 85)
Age (years), mean (SD)	36.8 (13.5)	37.2 (15.3)
Male, n (%)	51 (54.8)	44 (51.8)
Race[a], n (%)		
White	68 (73.1)	68 (73.1)
Asian	17 (18.3)	9 (10.6)
Black or African American	8 (8.6)	9 (10.6)
Other	0 (0.0)	1 (1.2)
Baseline		
EASI, mean (SD)	25.8 (9.7)	24.9 (9.0)
DLQI, mean (SD)	15.9 (7.3); *N = 92*	14.3 (7.1); *N = 83*
Worst daily pruritus NRS, mean (SD)	7.5 (1.5); *N = 92*	7.5 (1.6); *N = 84*
Eczema-related sleep interference NRS (weekly), mean (SD)	6.7 (2.1); *N = 92*	6.6 (2.2) ; *N = 84*
Week 16 response		
EASI, mean (SD)	2.1 (2.4)	1.9 (2.0)
DLQI, mean (SD)	3.1 (3.1); *N = 90*	3.4 (3.6); *N = 81*
Worst daily pruritus NRS, mean (SD)	2.7 (2.1); *N = 88*	3.1 (2.2); *N = 75*
Eczema-related sleep interference NRS (weekly), mean (SD)	2.1 (2.1); *N = 88*	2.2 (2.2); *N = 75*

[a]One patient with missing data in Week 16 responder group re-randomized to tralokinumab 300 mg Q4W.

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Results

Sustained improvements in DLQI in patients re-randomized to Q4W dosing at Week 16

- Patients achieved no-to-small effect on QoL at Week 16 with initial tralokinumab Q2W; improvements were sustained for up to 1 year with both Q2W and Q4W dosing options (**Figure 1A**)
  - Sensitivity analysis using LOCF showed comparable results (**Figure 1B**)

Sustained improvements in itch and sleep in patients re-randomized to Q4W dosing at Week 16

- Patients achieved no-to-mild effect in itch and sleep at Week 16 with tralokinumab Q2W; improvements were sustained for up to 1 year with both Q2W and Q4W dosing options (**Figure 2A and 3A**)
  - Sensitivity analysis using LOCF showed comparable results (**Figure 2B and Figure 3B**)

Figure 1 Sustained improvement in DLQI from Weeks 16-52 among patients re-randomized to tralokinumab Q2W or Q4W

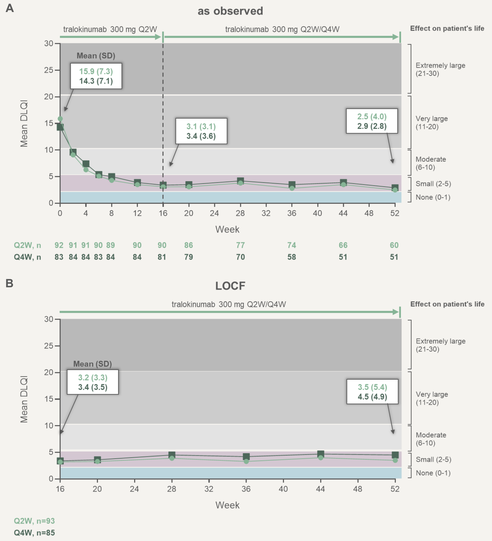


Figure 2 Sustained improvement in itch from Weeks 16-52 among patients re-randomized to tralokinumab Q2W or Q4W

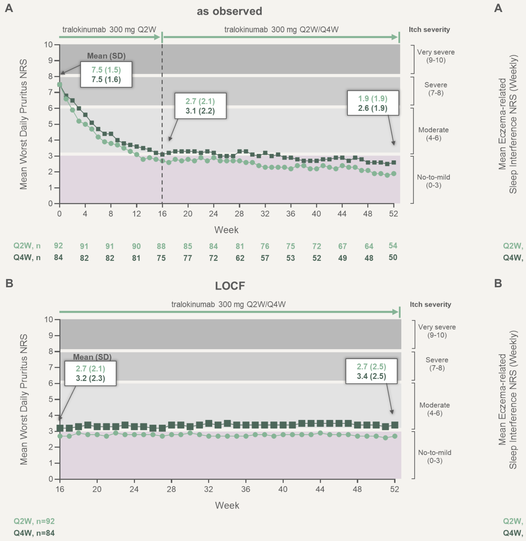
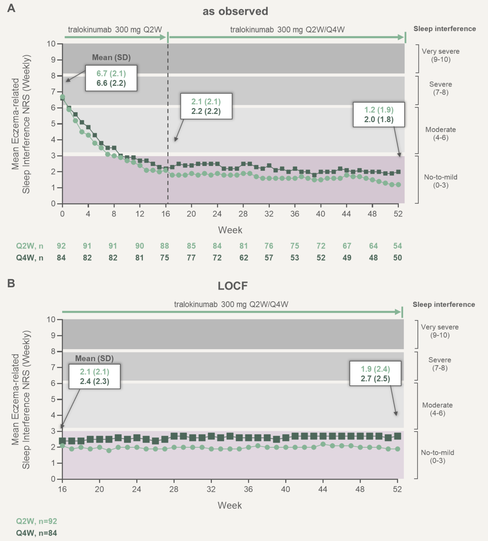


Figure 3 Sustained improvement in sleep from Weeks 16-52 among patients re-randomized to tralokinumab Q2W or Q4W



Abbreviations AD, atopic dermatitis; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; IGA 0/1, clear skin/almost clear skin; LOCF, last observation carried forward; N, total number of patients in indicated group; n, number of patients meeting indicated metric; NRS, Numerical Rating Scale; Q2W, once every two weeks; Q4W, once every 4 weeks; QoL, quality of life; SD, standard deviation; TCS, topical corticosteroids.

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