Tralokinumab Treatment In Patients With Atopic Dermatitis and Moderate-to-Severe Hand Involvement: Results From the 32-week Phase 3b ADHAND Trial

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Key Takeaways

- Tralokinumab monotherapy rapidly and significantly improved signs, symptoms and quality of life in patients with atopic dermatitis (AD) and moderate-to-severe hand involvement
- Response rates continued to improve through Week 32
- Tralokinumab was well tolerated with a favorable safety profile consistent with previous clinical trials
- These results support tralokinumab as a treatment option for this high-burden, difficult-to-treat population of patients with AD

Objective

- To evaluate the 32-week efficacy and safety of tralokinumab compared with placebo in patients with AD and moderate-to-severe hand involvement, who were candidates for systemic therapy

Background

- AD with hand involvement imposes a significant burden on individuals, affecting quality of life, emotional well-being, and ability to work[1-3]
- Hand involvement occurs in up to 56% of patients with AD, and reported by 58% of patients to be the most bothersome lesion location[1,2]
- Hand involvement in AD is often difficult to treat[3-4]
- There is a clear, unmet need for long-term treatments with a favorable benefit-risk profile for patients with AD and hand involvement

Methods (cont'd)

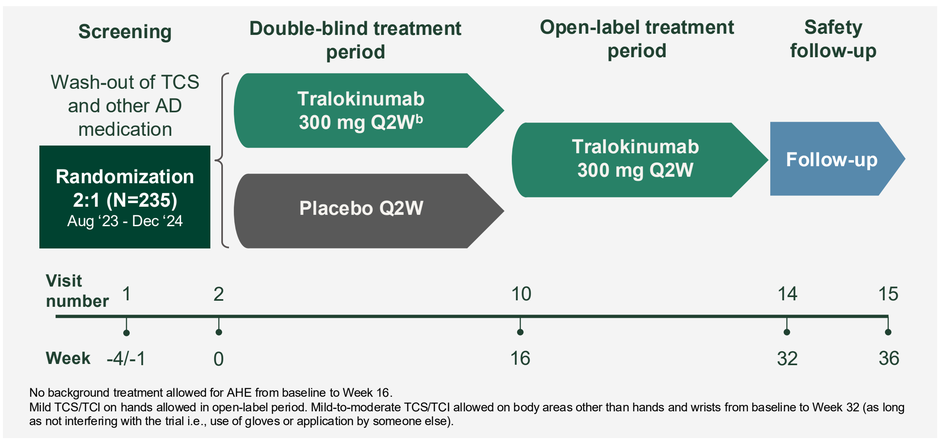
- ADHAND (NCT05958407)[5] was a phase 3b, interventional, international, multicenter, randomized, 32-week, double-blind, placebo-controlled, parallel-group, adaptive clinical trial with a 16-week, open-label treatment period of tralokinumab monotherapy in adults with AD and moderate-to-severe hand involvement, who were candidates for systemic therapy

Study eligibility and key endpoints|

Inclusion criteria[a]
- Adult patients with moderate-to-severe AHE (IGA-AHE 3 or 4)
- HESD itch score (weekly average) score of ≥4 at baseline
- Recent (within 1 year) inadequate response to topical prescription medications
- AD involvement of ≥1 body location other than hands/wrists

Primary endpoint
- IGA-AHE 0 or 1 at Week 16

Key secondary endpoints
- HECSI-50/-75/-90 at Week 16
- ≥4-point reductions in HESD itch and pain scores from baseline to Week 16
- Percentage changes in HECSI, HEIS, DLQI scores from baseline to Week 16



No background treatment allowed for AHE from baseline to Week 16.
Mild TCS/TCI on hands allowed in open-label period. Mild-to-moderate TCS/TCI allowed on body areas other than hands and wrists from baseline to Week 32 (as long as not interfering with the trial i.e., use of gloves or application by someone else).

[a]Exclusion criteria included: Active subtypes of hand eczema other than atopic hand eczema (AHE) considered to be the predominant cause of the current handeczema, prior failure on tralokinumab (lack of efficacy or safety concern) or dupilumab (lack of efficacy), use of systemic medication within the prior 4 weeks or topical medication within the prior 1 week of trial start. [b]Participants in the tralokinumab group received a loading dose of 600 mg on Day 1.

Results

Patients

- See the **online supplement** via the QR code for details of patient disposition, baseline demographics and disease characteristics and the use of rescue medication

Clinician-reported outcomes

Investigator Global Assessment – Atopic Hand Ezema (IGA-AHE)

- The **primary endpoint** was met at Week 16, with 40.0% of patients who received tralokinumab achieving **IGA-AHE 0/1** compared with 10.6% of patients who received placebo (treatment difference [95% CI]: 29.7% [19.0, 40.4], *P*<0.001; **Figure 1; Table 1**)
  - Response rates continued to improve through Week 32, with 57.9% (77/133) of patients continuing tralokinumab achieving IGA-AHE 0/1 (as observed)

Hand Eczema Severity Index (HECSI)

- The number of patients achieving **HECSI-50, HECSI-75** or **HECSI-90** was significantly greater for tralokinumab compared with placebo at Week 16 (**Table 1**)
  - 41.7% of patients who received tralokinumab achieved **HECSI-90** compared with 10.9% of patients who received placebo (treatment difference [95% CI]: 30.8% [20.0, 41.5], *P*<0.001); **Figure 2**; **Table 1**)
- Further improvements were observed through Week 32 on all HECSI outcomes

Table 1 Primary and key secondary endpoints

	Double-blind period at Week 16[a]			Open-label period at Week 32 (OC)[c]	
	Tralo (N=156)	Pbo (N=79)	*P* value	Tralo–Tralo, % (N=133)	Pbo–Tralo, % (N=67)
Proportion of patients, % (95% CI)					
IGA-AHE 0/1	**40.0** (31.3, 49.4)	**10.6** (5.0, 20.9)	*<0.001*	57.9	58.2
HECSI-50	**79.7** (71.9, 85.8)	**50.7** (38.7, 62.7)	*<0.001*	94.0	92.5
HECSI-75	**64.1** (55.3, 72.0)	**33.8** (23.4, 46.0)	*<0.001*	77.4	76.1
HECSI-90	**41.7** (33.0, 50.9)	**10.9** (5.2, 21.4)	*<0.001*	63.9	59.7
HESD itch ≥4, [n][b]	**47.3** (38.4, 56.4) [153]	**20.7** (12.6, 31.9) [78]	*<0.001*	59.7 [124]	66.1 [56]
HESD pain ≥4 [n][b]	**45.3** (36.0, 55.0) [138]	**13.3** (7.1, 23.4) [73]	*<0.001*	74.3 [113]	64.7 [51]
Mean change from baseline, % (95% CI)					
HECSI	**−69.9** (−77.5, −62.3)	**−31.4** (−42.2, −20.6)	*<0.001*	−86.3	−83.6
HEIS [n]	**−64.9** (−71.1, −58.7) [154]	**−28.5** (−37.4, −19.7) [77]	*<0.001*	−75.7 [130]	−76.2 [62]
DLQI [n]	**−60.9** (−68.8, −53.0) [154]	**−21.0** (−32.1, −9.9) [77]	*<0.001*	−72.9 [129]	−73.0 [62]

[a]Binary endpoints were analyzed using NRI for data following discontinuation due to an AE or lack of efficacy. Data following all other reasons for discontinuation was set to missing and, together with any other missing data, was imputed from a linear model using MI. Continuous endpoints were analyzed using last observation carried forward (LOCF) for data following discontinuation due to an AE or lack of efficacy and data after receipt of rescue medication. Data following all other reasons for discontinuation was set to missing and, together with any other missing data, was imputed from a linear model using MI. [b]Only patients with a baseline value ≥4 were included in the analysis. [c]Data analyzed as OC.

Patient-reported outcomes

Hand Eczema Symptom Diary (HESD) itch and pain

- At Week 16, significantly more patients achieved a **≥4-point reduction** in **HESD itch** and **HESD pain** with tralokinumab compared with placebo (**HESD itch** treatment difference: 26.6% [95% CI: 14.6, 38.7]; *P*<0.001; **HESD pain** treatment difference: 32.0% [95% CI: 20.8, 43.1] *P*<0.001; **Table 1**)
  - Further improvements in **HESD itch** and **pain** were observed through Week 32 (**Table 1**)
- The mean **percentage change from baseline** in **HESD itch** and **HESD pain** was greater for tralokinumab compared with placebo from Week 1 and onwards (See **online supplement** via the QR code)

Safety

- The proportion of patients experiencing at least one adverse event (AE) was comparable between tralokinumab (60.3%) and placebo (60.8%) (**Table 2**)
- Safety data for patients who switched from placebo to tralokinumab are available in the **online supplement**

Figure 1 Proportion of responders with IGA-AHE 0/1 (clear/almost clear skin) up to Week 32

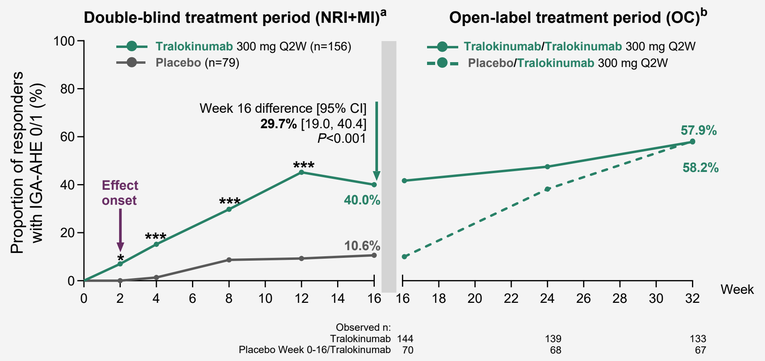
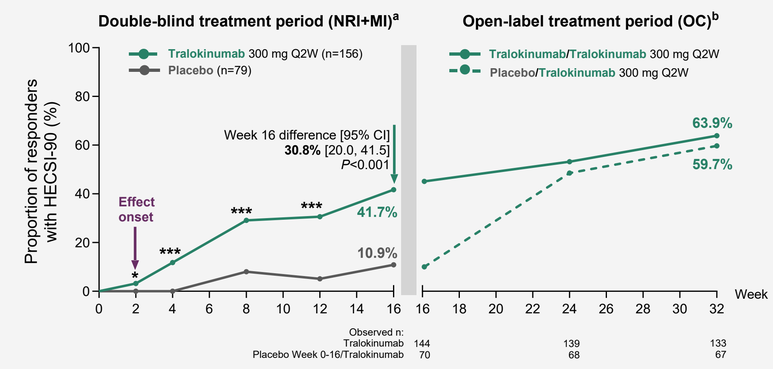


Figure 2 Proportion of responders with HECSI-90 up to Week 32



*P≤0.01. ***P≤0.001.
[a]Results from a logistic regression model on the two cohorts of patients randomized before and after sample size re-calculation are combined using a combination-test with equal weights. Non-responder imputation (NRI) was used for data after rescue, and data after discontinuation due to AE or lack of efficacy. MI was used following other reasons for discontinuation, and for other missing data. [b]Data analyzed as observed cases (OC).

Clinical images of tralokinumab-treated patients

- Clinical images showing improvement of AD in tralokinumab-treated patients are shown in **Figures 3** and **4**

Table 2 Safety summary

Category, n (%)	Double-blind period		Open-label period
	Tralo (N=156)	Pbo (N=79)	Tralo–Tralo (N=144)
All AEs	94 (60.3)	48 (60.8)	63 (43.8)
Mild	72 (46.2)	28 (35.4)	42 (29.2)
Moderate	48 (30.8)	25 (31.6)	31 (21.5)
Severe	2 (1.3)	3 (3.8)	2 (1.4)
Serious AEs	3 (1.9)	1 (1.3)	2 (1.4)
AE leading to withdrawal	3 (1.9)	2 (2.5)	1 (0.7)
Most frequent AEs (≥3% in any group)			
Nasopharyngitis	26 (16.7)	6 (7.6)	12 (8.3)
COVID-19	8 (5.1)	0	0
Upper respiratory tract infection	6 (3.8)	4 (5.1)	4 (2.8)
Conjunctivitis	5 (3.2)	2 (2.5)	2 (1.4)
Injection site reaction	10 (6.4)	1 (1.3)	8 (5.6)
Fatigue	5 (3.2)	3 (3.8)	0
Dermatitis atopic	9 (5.8)	4 (5.1)	4 (2.8)
Hand dermatitis	2 (1.3)	7 (8.9)	4 (2.8)

Figure 3 Male patient treated with tralokinumab

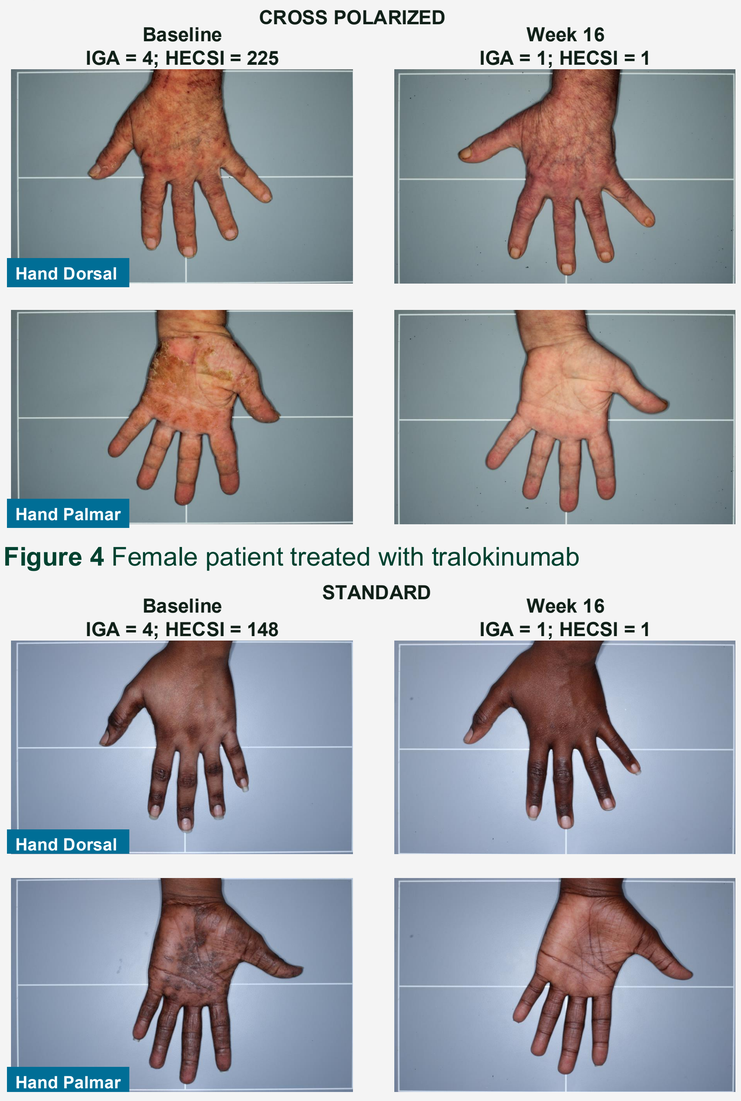


Figure 4 Female patient treated with tralokinumab

Abbreviations AD, atopic dermatitis; AE, adverse event; AHE, atopic hand eczema; CI, confidence interval; DLQI, Dermatology Quality of Life Index; HECSI, Hand Eczema Severity Index; HESCI-50/-75/-90, 50%/75%/90% decrease in HESCI; HEIS, Hand Eczema Impact Scale; HESD, Hand Eczema Symptom Diary; IGA-AHE, Investigator Global Assessment-atopic hand eczema; LOCF, last observation carried forward; MI, multiple imputation; n, number of patients with recorded observation; N, number of patients in indicated treatment set; NRI, non-responder imputation; OC, observed cases; Q2W, every 2 weeks; TCI, topical calcineurin inhibitor; TCS, topical corticosteroid.

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