Tralokinumab Significantly Reduces Work Productivity Impairment and Daily Activity Impairment in Adults With Atopic Dermatitis and Moderate-to-Severe Hand Involvement

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Conclusions

- In adults with AD and moderate-to-severe hand involvement, tralokinumab provided rapid and significant reductions in Work Productivity Impairment and Daily Activity Impairment scores compared with placebo
- Onset of tralokinumab efficacy was observed as early as Week 2 (the earliest timepoint measured)
- These findings highlight the broader functional and psychosocial benefits of tralokinumab and reinforce its potential as an effective treatment option for these patients

Objective

- Evaluate the impact of tralokinumab on work productivity impairment and daily activity impairment in participants with atopic dermatitis (AD) with moderate-to-severe hand involvement over the 16-week, double-blind treatment period of the ADHAND trial

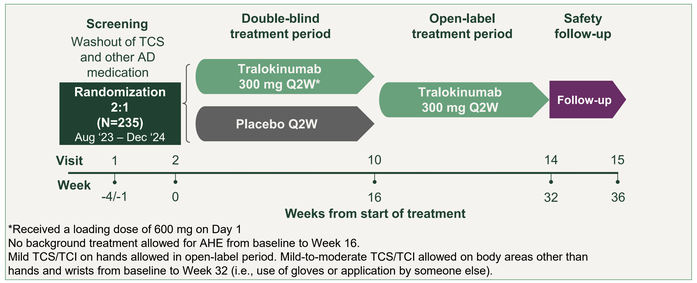
Background

- Moderate-to-severe AD typically affects multiple body regions, with certain areas being more visible and particularly burdensome[1,2]
- Hand involvement is present in most AD patients and can interfere with their ability to carry out daily activities and work[2,3]
- AD with hand involvement can be difficult to treat, and there remains an unmet need for long-term treatments with a favorable benefit-risk profile[3]
- Tralokinumab, a monoclonal antibody specifically targeting interleukin-13, has demonstrated efficacy and safety in phase 3 trials of up to 5 years in adults and adolescents with moderate-to-severe AD[4-7]
  - Interim Week 16 results of the ADHAND study showed that tralokinumab significantly improved the extent and severity of hand eczema lesions, and patient reported outcomes including itch, pain and health-related quality of life in adults with AD and moderate-to-severe hand involvement[8]

Methods

- ADHAND (NCT05958407) is a phase 3b, interventional, international, multi-center, randomized, 16-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 (**Figure 1**)

Figure 1 ADHAND study design



*Received a loading dose of 600 mg on Day 1
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 (i.e., use of gloves or application by someone else).

- **Key inclusion criteria**: adults with moderate-to-severe atopic hand eczema (IGA-AHE 3 or 4); HESD itch score (weekly average) ≥4; recent (<1 year) inadequate response to topical prescription medications; AD involvement of ≥1 body location other than hands/wrists
- **Key exclusion criteria**: prior failure on tralokinumab (lack of efficacy or safety concern) or dupilumab (lack of efficacy)
- **Outcomes:** Participants completed the **Work Productivity and Activity Impairment plus Classroom Impairment Questionnaire for Atopic Hand Eczema (WPAI+CIQ:AHE)**
  - Analyses of the WPAI+CIQ:AHE assessed change from baseline in:
    - **Activity Impairment** (answered by all participants; activities not related to work or school)
    - **Work Productivity Impairment** (answered by participants currently employed)
    - **Classroom Impairment** (answered by participants attending classes in an academic setting)[a]

[a]Classroom impairment was not analyzed due to the small number of answers to the CIQ.

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Results

Participants

- 235 participants were randomized to receive tralokinumab (n=156) or placebo (n=79) (**Table 1**)
  - Baseline clinical characteristics were comparable between groups, with high scores reported for Activity Impairment, Work Productivity Impairment, and Presenteeism

Table 1 Baseline demographics and clinical characteristics

	Tralokinumab (N=156)	Placebo (N=79)
Age, median (range), years	36 (18-81)	40 (19-73)
Female sex, n (%)	94 (60.3)	55 (69.6)
Severe IGA-AHE, n (%)	42 (26.9)	23 (29.1)
HECSI, mean (SD)	83.9 (51.8)	77.7 (41.4)
HESD itch, weekly mean (SD)	7.3 (1.6)	7.5 (1.7)
HESD pain, weekly mean (SD)	6.5 (2.2)	7.1 (2.2)
Currently employed, n (%)	111 (71.2)	58 (73.4)
WPAI+CIQ:AHE		
Activity Impairment score, n	154	77
Mean % (SD)	57.1 (26.9)	61.3 (27.0)
Work Productivity Impairment score, n	109	54
Mean % (SD)	51.9 (29.6)	48.3 (32.1)
Work Presenteeism score, n	109	54
Mean % (SD)	49.6 (28.7)	47.0 (31.8)
Work Absenteeism score, n	109	56
Mean % (SD)	8.1 (18.0)	8.7 (22.0)

Change in WPAI+CIQ:AHE scores from baseline to Week 16

- **Activity Impairment** (**Figure 2**). Reductions from baseline were significantly greater with tralokinumab versus placebo (mean [95% CI]):
  - Week 16, -36.3 versus -15.3 (difference: -21.0 [-27.9, -14.1]; *P*<.0001)
  - Week 2, -17.5 versus -6.3 (difference: -11.2; [-17.4, -5.0]; *P*<.001)
- **Work Productivity Impairment** (**Figure 3**). Reductions from baseline were significantly greater with tralokinumab versus placebo (mean [95% CI]):
  - Week 16, -26.7 versus -10.2 (difference: -16.4 [-25.0, -7.9]; *P*<.001)
  - Week 2, -11.8 versus -1.0 (difference: -10.8; [-18.7, -2.9]; *P*<.01)
- The reduction in Work Productivity Impairment was mainly driven by a reduction in **Presenteeism** score (impairment while working; **Figure 4**) rather than a reduction in **Absenteeism** score (work time missed; **Figure 5**).
  - The Absenteeism score at baseline was low (8.3%) for both groups

Figure 2 Change in **Activity Impairment** from baseline to Week 16

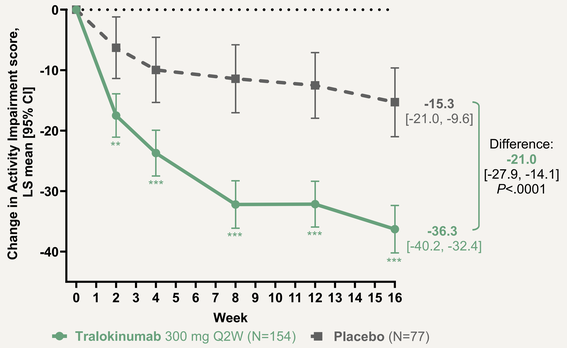


Figure 3 Change in **Work Productivity Impairment** from baseline to Week 16

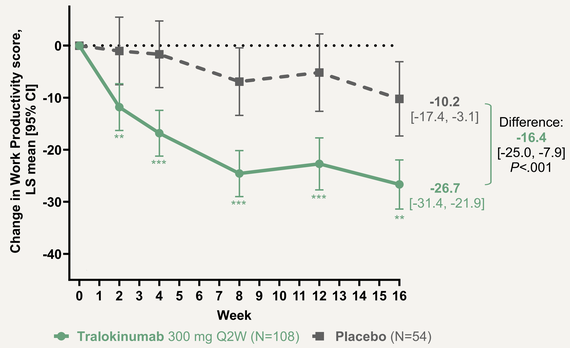


Figure 4 Change in **Presenteeism** (impairment while working) from baseline to Week 16

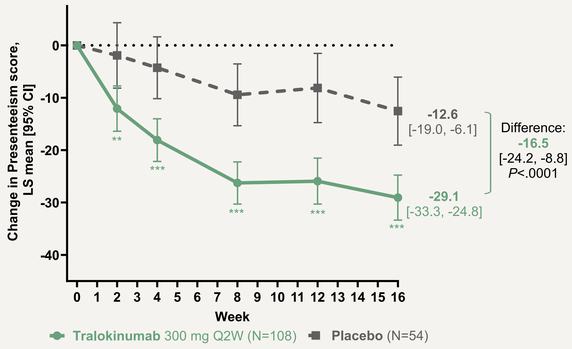
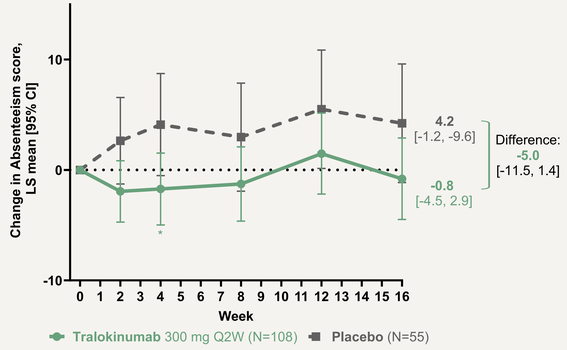


Figure 5 Change in **Absenteeism** (work time missed) from baseline to Week 16



*P <.05. ** P <.01. ***P<.001.
Data were analyzed using ANCOVA. LOCF was used for data after rescue, and missing data after discontinuation due to AE or lack of efficacy. MI used for other missing data.

Abbreviations AD, atopic dermatitis; AHE, atopic hand eczema; ANCOVA, analysis of covariance; CI, confidence interval; HECSI, Hand Eczema Severity Index; HESD, Hand Eczema Symptom Diary; IGA-AHE, Investigator's Global Assessment for Atopic Hand Eczema; IL-13, interleukin-13; LOCF, last observation carried forward; LS, least-square; MI, multiple imputation; N, number of patients in indicated treatment set; n, number of patients with recorded observation; SD, standard deviation; TCS, topical corticosteroid; TCI, topical calcineurin inhibitors; Q2W, once every two weeks; WPAI+CIQ:AHE, Work Productivity and Activity Impairment plus Classroom Impairment Questionnaire in Atopic Hand Eczema.

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