Tralokinumab is effective and well-tolerated in adults with atopic dermatitis with moderate-to-severe hand involvement who are candidates for systemic therapy: Week 16 results from the phase 3b ADHAND trial

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Objective

To assess the efficacy and safety of tralokinumab vs. placebo in patients who completed 16-week double-blind treatment in ADHAND

Presented by Teodora Festini MD

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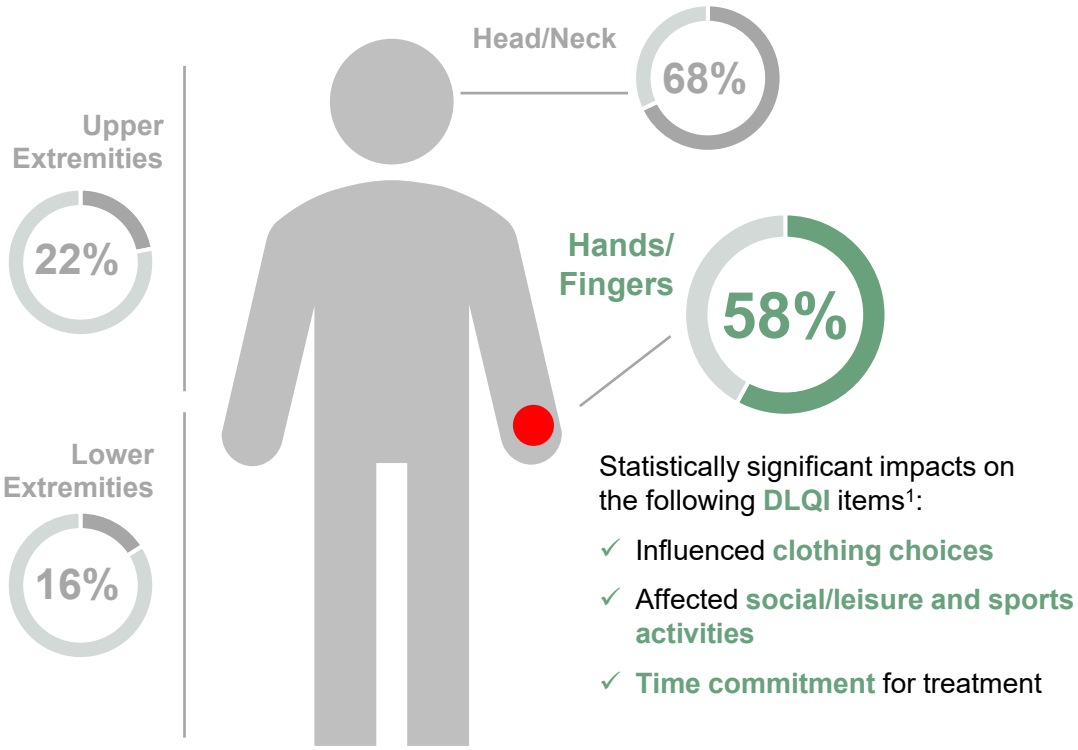
Background: AD with hand involvement causes significant impact on patient quality of life

Hand involvement in AD is bothersome for a large proportion of patients[1]



Statistically significant impacts on the following **DLQI** items[1]:

- ✓ Influenced **clothing choices**
- ✓ Affected **social/leisure and sports activities**
- ✓ **Time commitment** for treatment

- Hand involvement is present in a majority of patients with AD[2]
  - Often located on the wrists and back of hands where environmental exposures are frequent[3]
  - Up to two-thirds of cases are chronic[4]
  - One in three cases is classified as moderate-to-severe[2]
- AD with hand involvement imposes a significant burden on individuals, affecting quality of life, emotional well-being, and ability to work
- Hand involvement in AD is often difficult to treat
  - There is a clear unmet need for long-term treatments with a favorable benefit-risk profile

AD, atopic dermatitis; DLQI, Dermatology Quality of Life Index.

1. Lio PA, et al. *J Drugs Dermatol.* 2020;19(10):943-948. **2.** Silverberg JI, et al. *J Am Acad Dermatol.* 2023;89(3):519-528. **3.** Halling-Overgaard AS, et al. *Dermatol Clin*. 2017;35(3):365-372. **4.** Zhang J, et al. *J Invest Dermatol*. 2025;S0022-202X(25)00486-5.

ADHAND: A Phase 3b study of tralokinumab monotherapy in adults with AD and moderate-to-severe hand involvement who are candidates for systemic therapy*

Key inclusion and exclusion criteria

Inclusion criteria[1,a]

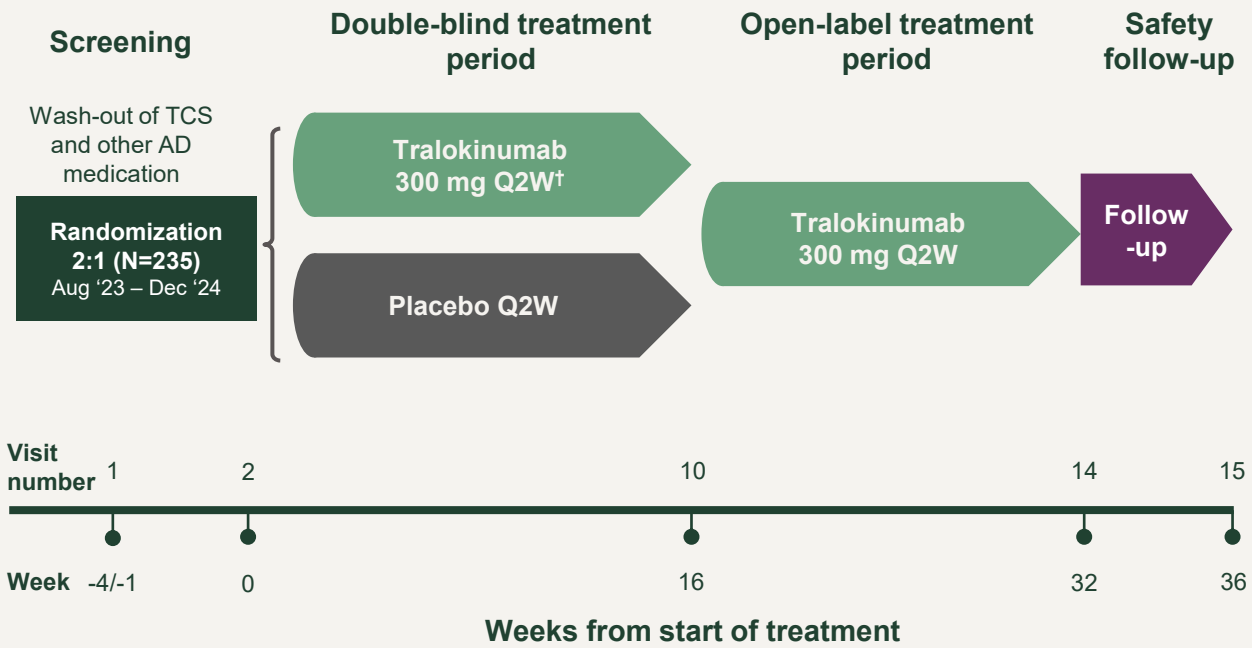
- Adult patients with moderate-to-severe AHE (IGA-AHE 3 or 4)
- HESD itch score (weekly average) score of ≥4 at baseline
- Recent (within 1 year) inadequate response to topical prescription medications
- AD involvement of ≥1 body location other than hands/wrists

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 (i.e., use of gloves or application by someone else).

*Patients with inadequate response or for whom topical treatments are contraindicated. [a]Exclusion criteria included; 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. †Participants in the tralokinumab group received a loading dose of 600 mg on Day 1.
AD, atopic dermatitis; AHE, atopic hand eczema; DLQI, Dermatology Life and Severity 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; N, number of patients in indicated treatment set; Q2W, every 2 weeks; TCI, topical calcineurin inhibitor; TCS, topical corticosteroid.
1. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT05958407. Updated February 2025. Accessed September 2025. NCT05958407.

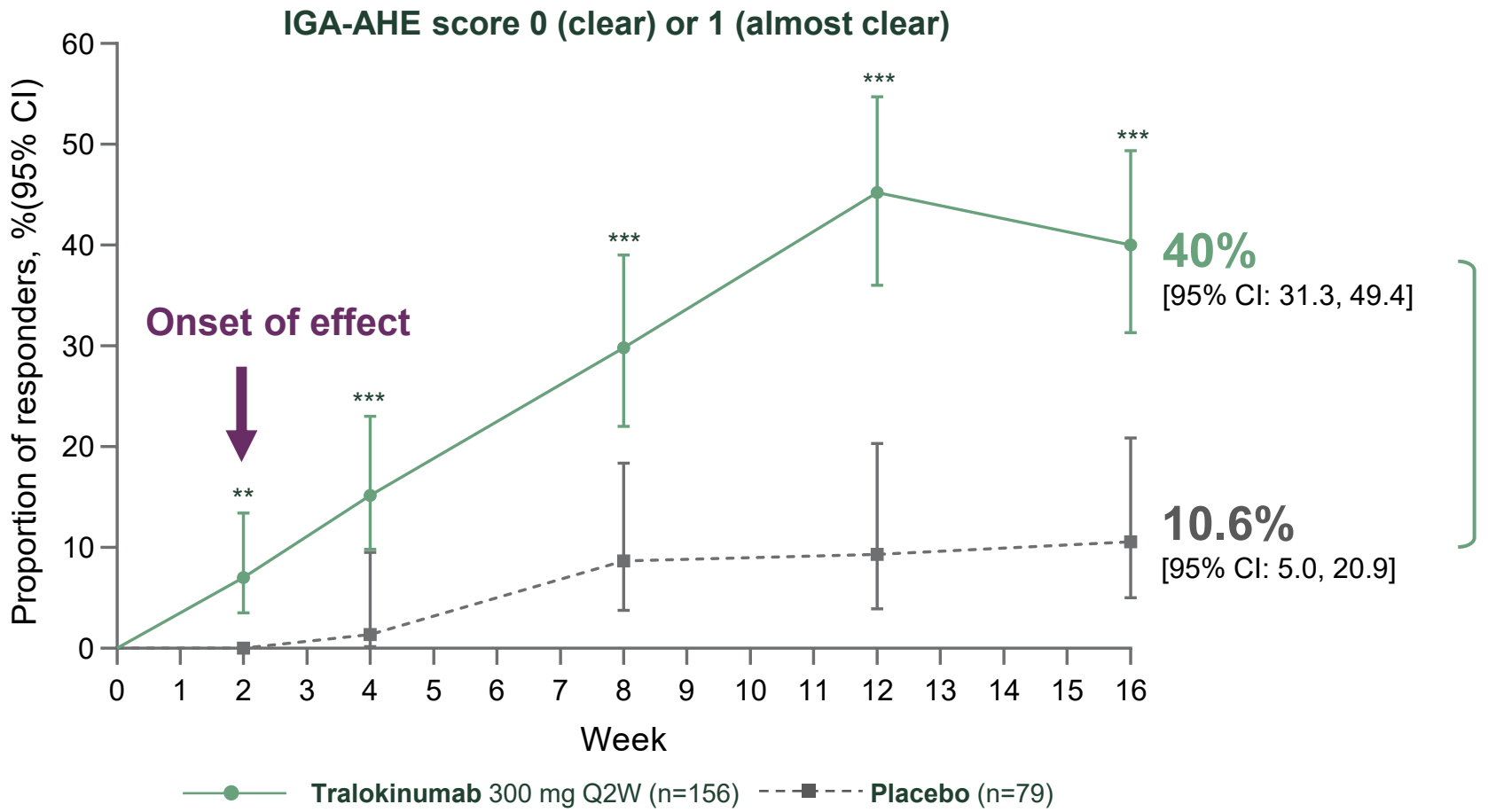
Baseline characteristics

- Most patients were White (67%) or Asian (24%)
- Median age at onset of AD was 14 years
- Median age at onset of hand involvement was 24 years
- All patients had received prior TCS therapy
  - 11.5% had previously received a biologic therapy

Demographics	Tralokinumab (N=156)	Placebo (N=79)	All (N=235)
Median age, years (min-max)	36.0 (18 - 81)	40.0 (19 - 73)	37.0 (18 - 81)
Female sex, n (%)	94 (60.3)	55 (69.6)	149 (63.4)
Median duration of AD, years (min-max)	17.5 (1 - 71)	23.0 (1 - 61)	20.0 (1 - 71)
Severe IGA-AHE, n (%)	42 (26.9)	23 (29.1)	65 (27.7)
HECSI, median (min-max)	68.5 (7 - 292)	67.0 (12 - 212)	68.0 (7 - 292)
HESD itch, median (min-max)	7.57 (3.4 - 10.0)	7.34 (4.2;10.0)	7.57 (3.4 - 10.0)
HESD pain, median (min-max)	7.00 (0.0 - 10.0)	7.34 (0.6 - 10.0)	7.14 (0.0 - 10.0)
DLQI, median (min-max)	13.0 (2 - 30)	14.0 (3 - 30)	13.0 (2;30)
HEIS, median (min-max)	2.56 (0.1 - 4.0)	2.89 (0.4 - 4.0)	2.67 (0.1 - 4.0)

AD, atopic dermatitis; AHE, atopic hand eczema; DLQI, Dermatology Life Quality Index; HEIS, hand eczema impact scale; HECSI, hand eczema and severity index; HESD, hand eczema symptom diary; IGA, investigator's global assessment; n, number of patients with recorded observation; N, number of patients in indicated treatment set; TCS, topical corticosteroid.

Primary endpoint: Proportion of responders with IGA-AHE 0/1 (clear or almost clear skin on hands) at Week 16



40%
[95% CI: 31.3, 49.4]

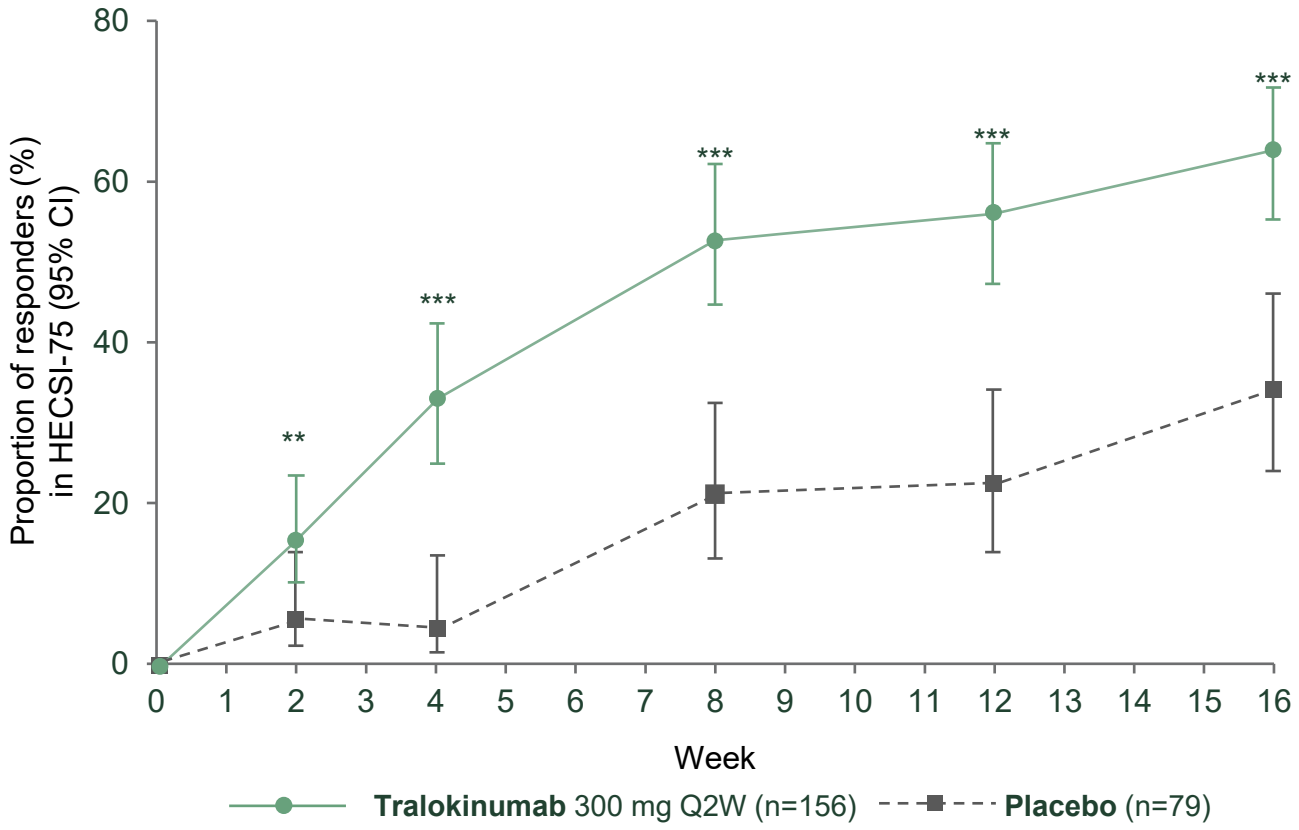
10.6%
[95% CI: 5.0, 20.9]

Difference:
29.7% [95% CI: 19.0, 40.4]
P< 0.001

***P* 0.002. ****P* < 0.001.
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. NRI was used for data after rescue, and missing data after discontinuation due to AE or lack of efficacy. MI used for other missing data.
AE, adverse event; AHE, atopic hand eczema; CI, confidence interval; IGA-AHE, Investigator Global Assessment-atopic hand eczema; MI, multiple imputation using a regression model; n, number of patients with recorded observation; NRI, non-responder imputation; Q2W, every 2 weeks.

Secondary endpoint: Proportion of responders achieving HECSI-75 at Week 16

Treatment success: Having a decrease in HECSI of at least 75% (HECSI-75) from baseline to Week 16



64.1%
[95% CI: 55.3, 72.0]

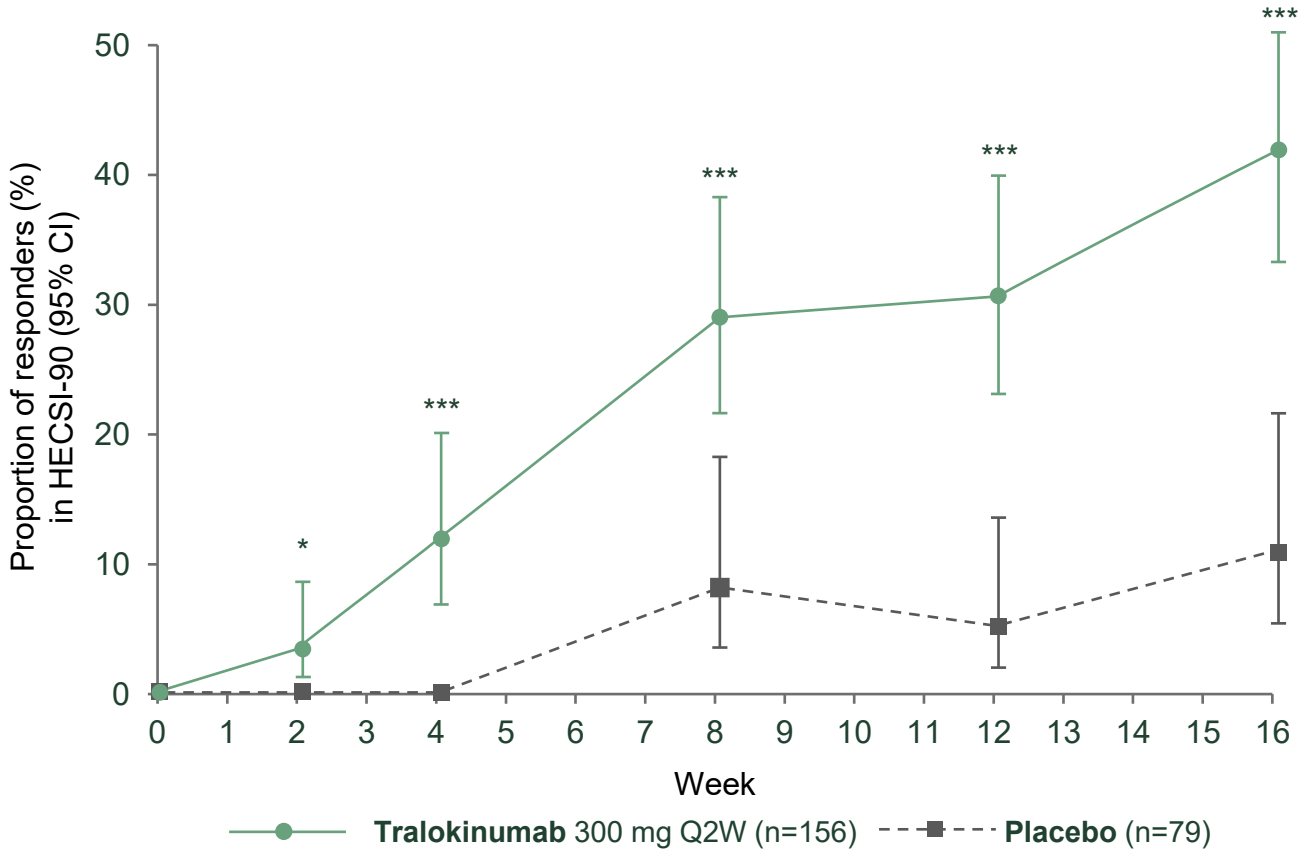
33.8%
[95% CI: 23.4, 46.0]

Difference:
30.3% [95% CI: 17.5, 43.0]
P< 0.0001

**$P \leq 0.01$. ***$P \leq 0.001$.
Data were analyzed using a Logistic regression model. NRI was used for data after rescue, and missing data after discontinuation due to AE or lack of efficacy. MI used for other missing data.
AE, adverse event; CI, confidence interval; HECSI, hand eczema area and severity index; HECSI-75, having a decrease in HECSI of at least 75% from baseline; MI, multiple imputation using a regression model; n, number of patients with recorded observation; NRI, non-responder imputation; Q2W, every 2 weeks.

Secondary endpoint: Proportion of responders achieving HECSI-90 at Week 16

Treatment success: Having a decrease in HECSI of at least 90% (HECSI-90) from baseline to Week 16



41.7%
[95% CI: 33.0, 50.9]

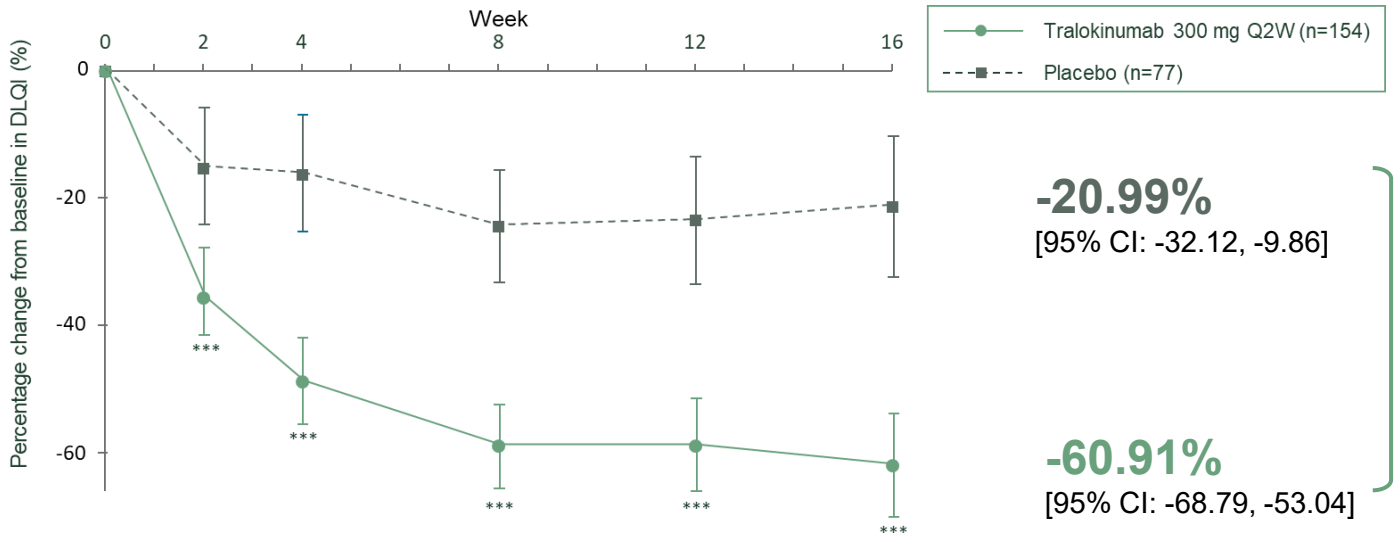
10.9%
[95% CI: 5.2, 21.4]

Difference:
30.8% [95% CI: 20.0, 41.5]
P< 0.0001

*$P \leq 0.05$. ***$P \leq 0.001$
Data were analyzed using a Logistic regression model. NRI was used for data after rescue, and missing data after discontinuation due to AE or lack of efficacy. MI used for other missing data.
AD, atopic dermatitis; ; AE, adverse event; CI, confidence interval; HECSI, hand eczema area and severity index; HECSI-90, having a decrease in HECSI of at least 90% from baseline; IGA-AHE, investigators global assessment for atopic hand eczema; MI, multiple imputation using a regression model; n, number of patients with recorded observation; NRI, non-responder imputation; Q2W, every 2 weeks.

Statistically significant improvements in patient-reported quality of life measures with tralokinumab throughout 16-week treatment period

Percentage change in **DLQI** from baseline to Week 16

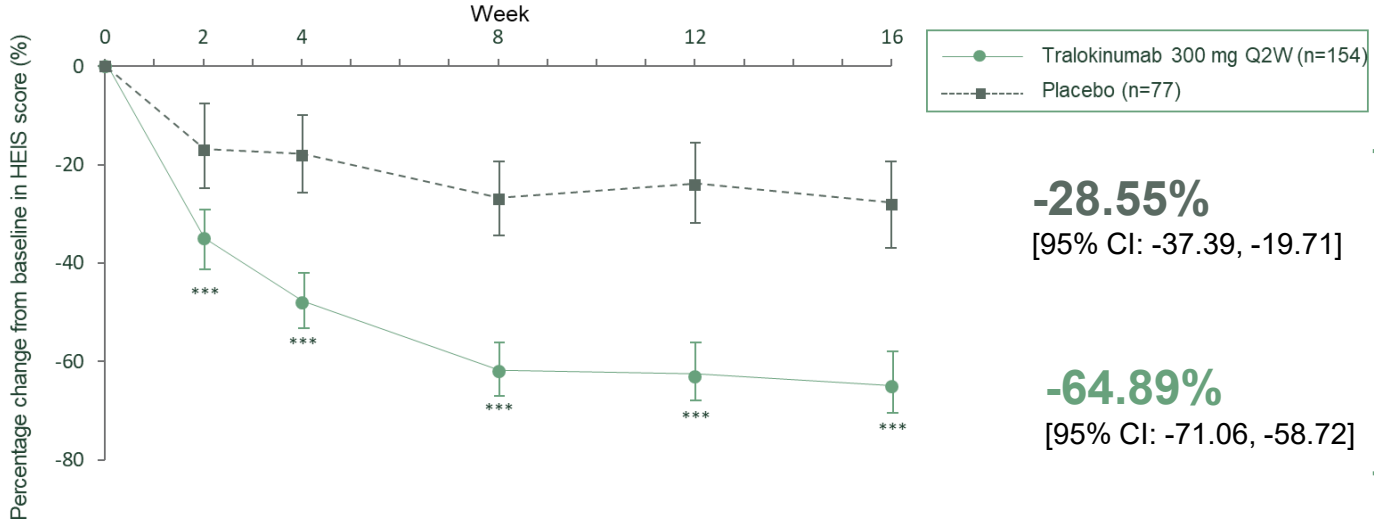


-20.99%
[95% CI: -32.12, -9.86]

-60.91%
[95% CI: -68.79, -53.04]

Difference:
-39.92% [95% CI: -53.54, 26.31]
P< 0.0001

Percentage change in **HEIS** from baseline to Week 16



-28.55%
[95% CI: -37.39, -19.71]

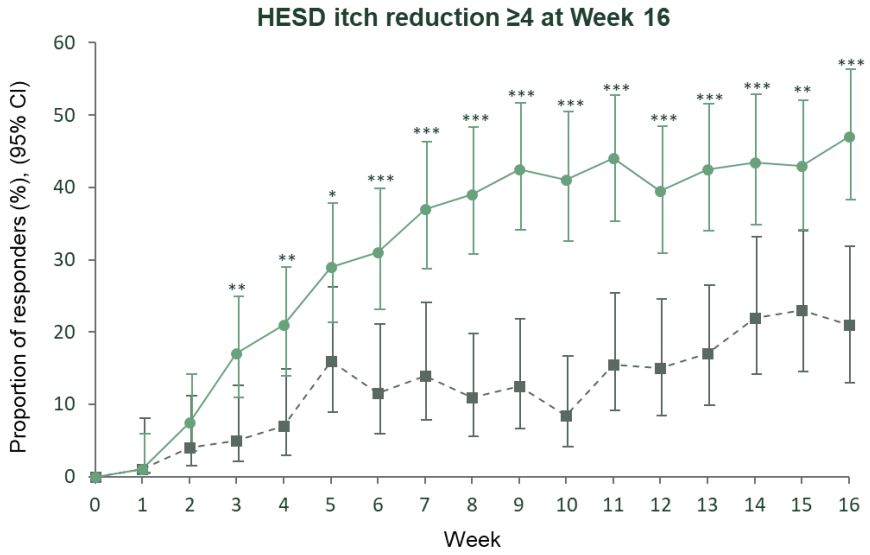
-64.89%
[95% CI: -71.06, -58.72]

Difference:
-36.34% [95% CI: -47.14, -25.55]
P< 0.0001

***$P \leq 0.0001$.
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.
AE, adverse event; ANCOVA, analysis of covariance; CI, confidence interval; DLQI, Dermatology Life Quality Index; HEIS, Hand Eczema Impact Scale; LOCF, Last Observation Carried Forward; MI, multiple imputation using a regression model; n, number of patients with recorded observation; Q2W, every 2 weeks.

Statistically significant improvements in HESD itch and HESD pain measures with tralokinumab throughout 16-week treatment period

≥4-point reduction in **HESD itch**

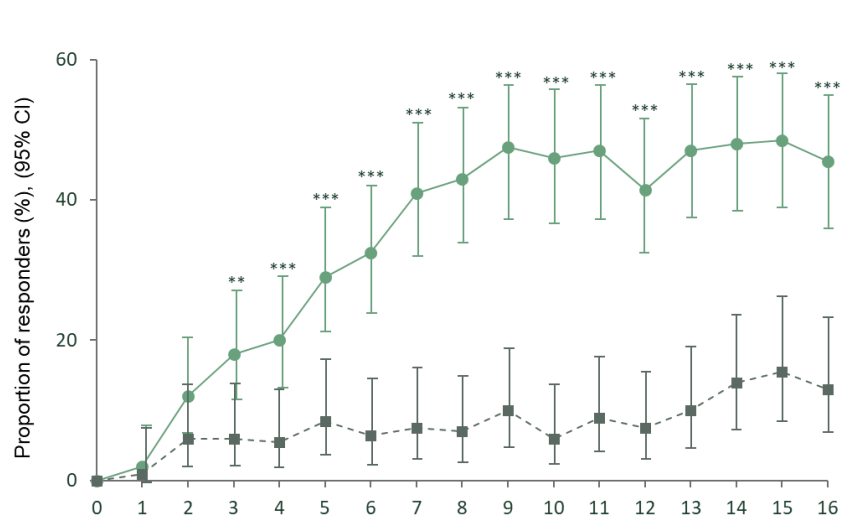


47.3%
[95% CI: 38.4, 56.4]

20.7%
[95% CI: 12.6, 31.9]

Difference:
26.6% [95% CI: 14.6, 38.7]
P< 0.0001

≥4-point reduction in **HESD pain**



45.3%
[95% CI: 36.0, 55.0]

13.3%
[95% CI: 7.1, 23.4]

Difference:
32.0% [95% CI: 20.8, 43.1]
P< 0.0001

*$P \leq 0.05$. **$P \leq 0.01$. ***$P \leq 0.0001$
Data were analyzed using a Logistic regression model. NRI was used for data after rescue, and missing data after discontinuation due to AE or lack of efficacy. MI used for other missing data.
AE, adverse event; CI, confidence interval; HESD, hand eczema symptom diary; MI, multiple imputation using a regression model; n, number of patients with recorded observation; NRI, non-responder imputation; Q2W, every 2 weeks.

Safety profile consistent with placebo, with no new safety signals identified throughout 16-week treatment period

Adverse events	Tralokinumab (N=156, PYE=47.38)			Placebo (N=79, PYE=23.17)		
	n (%)	No. events	R	n (%)	No. events	R
All AEs	94 (**60.3**)	263	**555.12**	48 (**60.8**)	91	**392.83**
Mild	72 (**46.2**)	178	**375.71**	28 (**35.4**)	52	**224.48**
Moderate	48 (**30.8**)	83	**175.19**	25 (**31.6**)	36	**155.41**
Severe	2 (**1.3**)	2	**4.22**	3 (**3.8**)	3	**12.95**
Serious adverse events	3 (**1.9**)	3	**6.33**	1 (**1.3**)	2	**8.63**
Probably or possibly related to study drug	49 (**31.4**)	102	**215.29**	12 (**15.2**)	22	**94.97**
Leading to trial withdrawal	3 (**1.9**)	4	**8.44**	2 (**2.5**)	2	**8.63**
All AESI	6 (**3.8**)	7	**14.77**	3 (**3.8**)	3	**12.95**
Conjunctivitis	6 (**3.8**)	6	**12.66**	3 (**3.8**)	3	**12.95**
Keratitis	1 (**0.6**)	1	**2.11**	0	0	0
AESI leading to trial withdrawal	0	0	0	0	0	0

AE, adverse event; AESI, adverse event of special interest; n, number of patients with recorded observation; N, number of patients in indicated treatment set; PYE, patient years of exposure; Q2W, every 2 weeks; R, rate.

Conclusions

- Tralokinumab met the primary and all secondary endpoints at Week 16
- Across all investigator-assessed and patient-reported outcomes, early onset of efficacy was observed by Week 2–3 of tralokinumab therapy
- Overall, tralokinumab was well-tolerated with an overall frequency of AEs consistent with placebo
  - No new safety signals were identified
- These results indicate tralokinumab is a potentially valuable treatment option for this hard-to-treat population of AD patients with moderate-to-severe hand involvement

Disclosures

- **Benjamin Ehst** has received fees/honoraria/royalities as an advisory board member, contributor and/or consultant for AbbVie, Amgen, AnaptysBio, Arcutis Biotherapeutics, Dermavant Sciences, Eli Lilly, Incyte, Janssen Biotech, LEO Pharma, Navigator Medicines, Novartis, Ortho Dermatologics, Priovant, Regeneron, Sanofi-Genzyme, UCB, and Up-To-Date; received speaking fees from AbbVie, BMS, Dermavant Sciences, Eli Lilly, Incyte, LEO Pharma, Novartis, National Psoriasis Foundation, Ortho Dermatologics, Regeneron, Sanofi-Genzyme and UCB; received institutional funding as an investigator for AbbVie, Allakos, Alumis, Amgen, Apogee, Arcutis Biotherapeutics, BMS, Celldex, Concert Pharmaceuticals, Dermavant Sciences, DermBiont, Eli Lilly, Incyte, Janssen Biotech, Kymab, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi-Genzyme, Sun Pharma, Takeda, UCB, and Ventyx Biosciences.
- **Richard Warren** has been a consultant and/or speaker for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, GlaxoSmithKline, Janssen, LEO Pharma, Novartis, Sanofi Genzyme, and UCB Pharma.
- **H. Chih-ho Hong** is a researcher, consultant, and/or advisor for AbbVie, Amgen, Arcutis, Aslan, Bausch Health, Boehringer Ingelheim, Bristol Meyers Squibb, Celgene, Dermavant, Dermira, DS Biopharma, Eli Lilly, Evelo, Galderma, GlaxoSmithKline, Incyte, JAMP pharma, Janssen, LEO Pharma, MedImmune, Organon, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, and UCB.
- **Juan Francisco Silvestre** has served as an investigator and/or speaker and/or advisor for following pharmaceutical companies: AbbVie, Almirall-Hermal, Amgen, Astra Zeneca, Eli-Lilly, Galderma, LEO Pharma, Incyte, Novartis, Pfizer, Regeneron, and Sanofi-Genzyme.
- **Dong-Hun Lee** has served as an investigator and/or speaker and/or advisor for AbbVie, Amgen, EHL Bio, Eli Lilly, Galderma, Incyte, Kangstem Bio, LEO Pharma, Novartis, Pfizer, and Sanofi.
- **Galina Balakirski** has been an advisor, speaker or investigator for AbbVie, Almirall, Amgen, Astra Zeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Eli Lilly, Galderma, Incyte, Janssen-Cilag, LEO Pharma, Menlo Therapeutics, MoonLake, Novartis, Pfizer, Sanofi, RHEACELL, UCB Pharma.
- **Andrei Metelitsa** has been a researcher, consultant, and/or advisor for AbbVie, Amgen, Arcutis, Bausch Health, Boehringer Ingelheim, Bristol Meyers Squibb, Celgene, Eli Lilly, Galderma, Incyte, JAMP pharma, Janssen, LEO Pharma, Organon, Novartis, Pfizer, Sanofi Genzyme, Sun Pharma, and UCB.
- **Niels Hoejsager Bennike** is an employee of LEO Pharma A/S.
- **Teodora Festini** is an employee of LEO Pharma A/S.
- **Farzaneh Safavimanesh** is an employee of LEO Pharma A/S.
- **Linda Stein-Gold** has served as a consultant, and/or has received payment for the development of educational presentations, and/or has received grants from Amgen, Arcutis, Bristol Myers Squibb, Dermavant Sciences, Inc., Eli Lilly, LEO Pharma, Ortho Dermatologics, Pfizer, and UCB Pharma. James Del Rosso has served as an advisor, research investigator, and/or speaker for AbbVie, Amgen, Arcutis, ASLAN Pharmaceuticals, Beiersdorf, Dermavant Sciences, Inc., Eli Lilly, Galderma, Incyte, L'Oréal, LEO Pharma, Nektar Therapeutics, Pfizer, Primus Pharmaceuticals, Regeneron, Sanofi, and Sun Pharma.

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