Tralokinumab provides long-term control of head and neck atopic dermatitis: end-of treatment results from the 5-year open-label ECZTEND study

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Objective

To assess the long-term efficacy of tralokinumab treatment on head and neck atopic dermatitis in patients followed for up to 5 years in ECZTEND.

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Introduction

- Atopic dermatitis (AD) is a chronic skin disease, which is particularly burdensome and difficult to treat when involving the head and neck (H&N)[1]
- Tralokinumab, a high-affinity monoclonal antibody that specifically targets interleukin-13, is approved for the treatment of moderate-to-severe AD in multiple countries[2-4]
- ECZTEND (NCT03587805) was an open-label 5-year extension study of tralokinumab 300 mg Q2W ± optional TCS/TCI enrolling patients ≥12 years with moderate-to-severe AD who completed one of multiple tralokinumab parent trials (ECZTRA 1-8 and the investigator-initiated study TraSki)[5]
- A previous interim analysis demonstrated progressive and sustained improvements in H&N AD in patients treated for up to 1 year in the parent trials ECZTRA 1&2 and up to 3 years in ECZTEND[6]

Objective

To assess the long-term efficacy of tralokinumab treatment on head and neck atopic dermatitis in patients followed for up to 5 years in ECZTEND.

AD, atopic dermatitis; H&N, head and neck; Q2W, every 2 weeks; TCI, topical calcineurin inhibitor; TCS, topical corticosteroid.

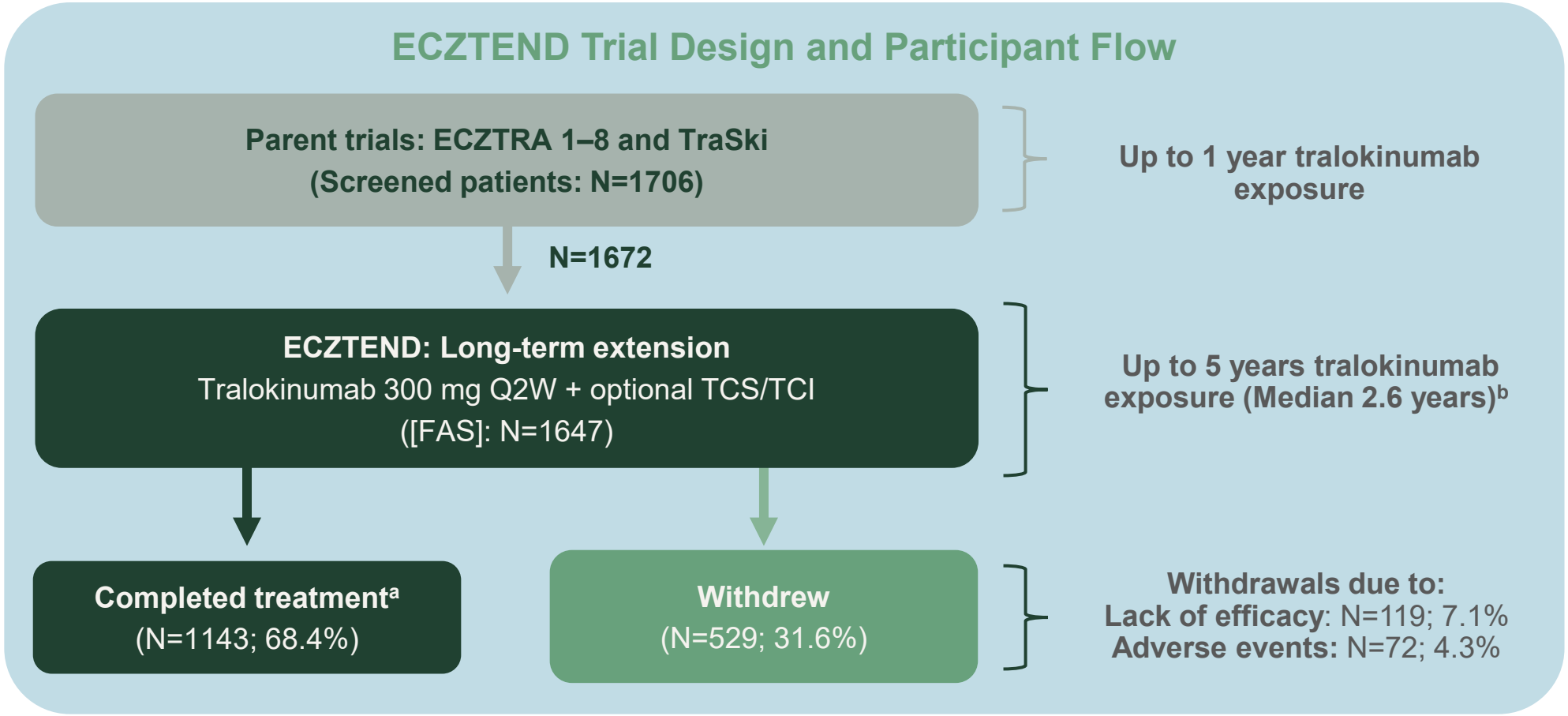
1. Silverberg JI, et al. *J Am Acad Dermatol*. 2023;89(3):519-528. 2. Bieber T. *Allergy*. 2020;75(1):54-62. 3. Wollenberg A, et al. *Br J Dermatol*. 2021;184(3):437-449. 4. Simpson EL, et al. *Am J Clin Dermatol*. 2024;25:139-148. 5. Blauvelt A, et al., *SKIN The Journal of Cutaneous Medicine*, 9(2), s573-s573. 6. Chovatiya R, et al. *Am J Clin Dermatol.* 2025;26(4):587-601.

Patient population and analyses

- This post hoc analysis included patients (N=1639) completing one of the parent trials ECZTRA 1–8 who were subsequently followed for up to 5 years in ECZTEND
  - 287 patients had received placebo in the parent trial
  - 236 patients had ≥16 weeks (5 half-lives of tralokinumab) between the last dose in the parent trial and first dose in ECZTEND
- Efficacy outcomes included:
  - Overall EASI and body region sub-scores (H&N, upper limb, trunk, lower limb)
  - Percentages of patients with H&N EASI ≥1 at parent trial baseline (N=1434) who achieved: H&N EASI-75 (≥75% improvement in H&N EASI), H&N EASI 0, H&N EASI ≤2, H&N EASI ≤1
- Results are presented using observed cases
  - Sensitivity analysis was performed for H&N EASI using the last observation carried forward (LOCF; missing values imputed) approach

AD, atopic dermatitis; EASI, Eczema Area and Severity Index; EASI-75, at least 75% improvement in EASI; FAS, full analysis set; H&N, head and neck; H&N EASI, EASI subscore for head and neck region; N, number of patients in indicated treatment set; LOCF, last observation carried forward.

Patient disposition



[a]Patients completed the trial if they completed the period of the trial they consented to or withdrew from the trial due to tralokinumab becoming commercially available in their country. [b]Protocol amendment in May 2021 prolonged the trial from up to 3 to up to 5 years.
AE, adverse event; FAS, full analysis set; GCP, good clinical practice; N, number of patients in indicated treatment set; Q2W, every 2 weeks; TCI, topical calcineurin inhibitor; TCS, topical corticosteroid.

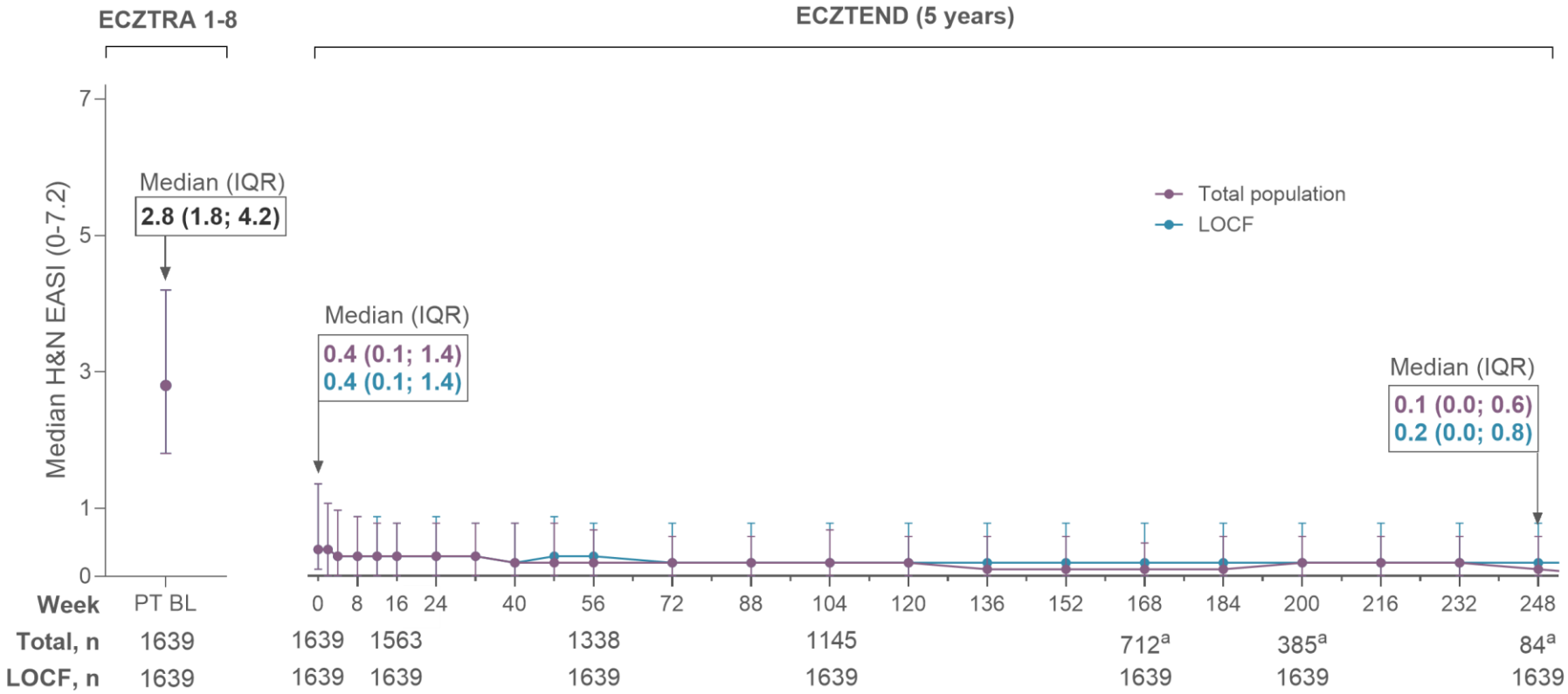
Parent trial baseline demographics and clinical characteristics

- At parent trial baseline, the median H&N EASI (range, 0–7.2) was 2.8 and 87.5% of patients exhibited H&N EASI ≥1

	Tralokinumab 300 mg Q2W (N = 1639[a])
Demographics	
Age (years), mean (SD)	37.2 (14.7)
Male, n (%)	945 (57.7)
BSA involvement (%), mean (SD)	50.8 (23.7)
Duration of AD (years), mean (SD)	27.6 (15.2)
Clinical characteristics	
IGA, n (%)	
3 (moderate)	866 (52.8%)
4 (severe)	773 (47.2%)
EASI, median (IQR)	27.1 (20.6;38.0)
H&N EASI (0–7.2), median (IQR)	2.8 (1.4; 4.2)
DLQI, median (IQR)	16.0 (11.0;21.0)
SCORAD, median (IQR)	67.9 (60.0;78.2)
Current or past atopic comorbidities, n (%)	
Asthma	841 (51.3%)
Food allergy	659 (40.2%)
Hay fever	949 (57.9%)

[a]Parent trial baseline data were not transferred to LEO Pharma from 8 patients included from the investigator-initiated trial.
AD, atopic dermatitis; BSA, body surface area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; H&N, head and neck; H&N EASI, EASI subscore for head and neck region; IGA, Investigator's Global Assessment; IQR, interquartile range; n, number of patients with recorded observation; N, number of patients in indicated treatment set; Q2W, every 2 weeks; SCORAD, SCORing AD; SD, standard deviation.

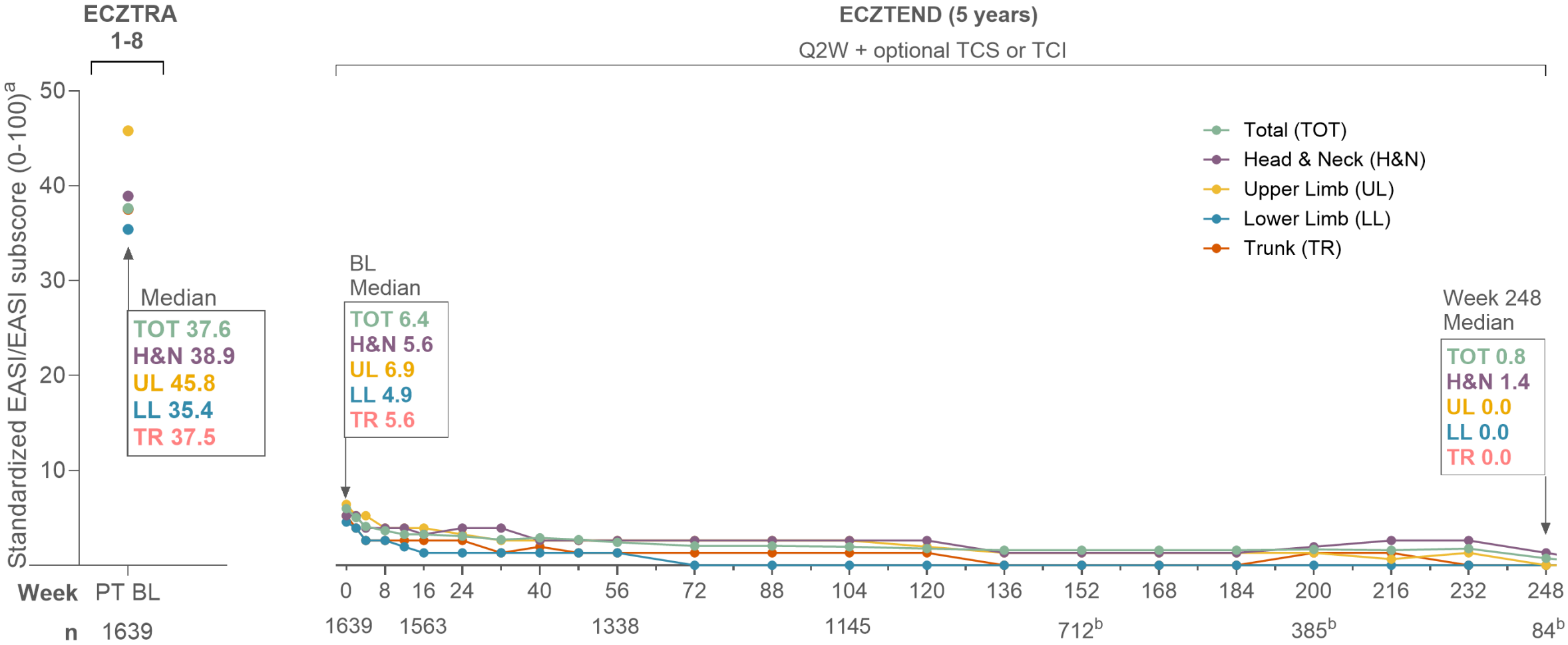
Tralokinumab provides meaningful and sustained improvement in H&N EASI for up to 5 years in ECZTEND



- Reduction in median [IQR] H&N EASI from 2.8 [1.8; 4.2] at parent trial baseline to 0.4 [0.1; 1.4] at ECZTEND trial start (n=1639), was maintained through Week 248 of ECZTEND (0.1 [0.0; 0.6], n=84)
- A sensitivity analysis using LOCF for missing data showed comparable results (median H&N EASI at Week 248: 0.2 [0.0; 0.8], n=1639)

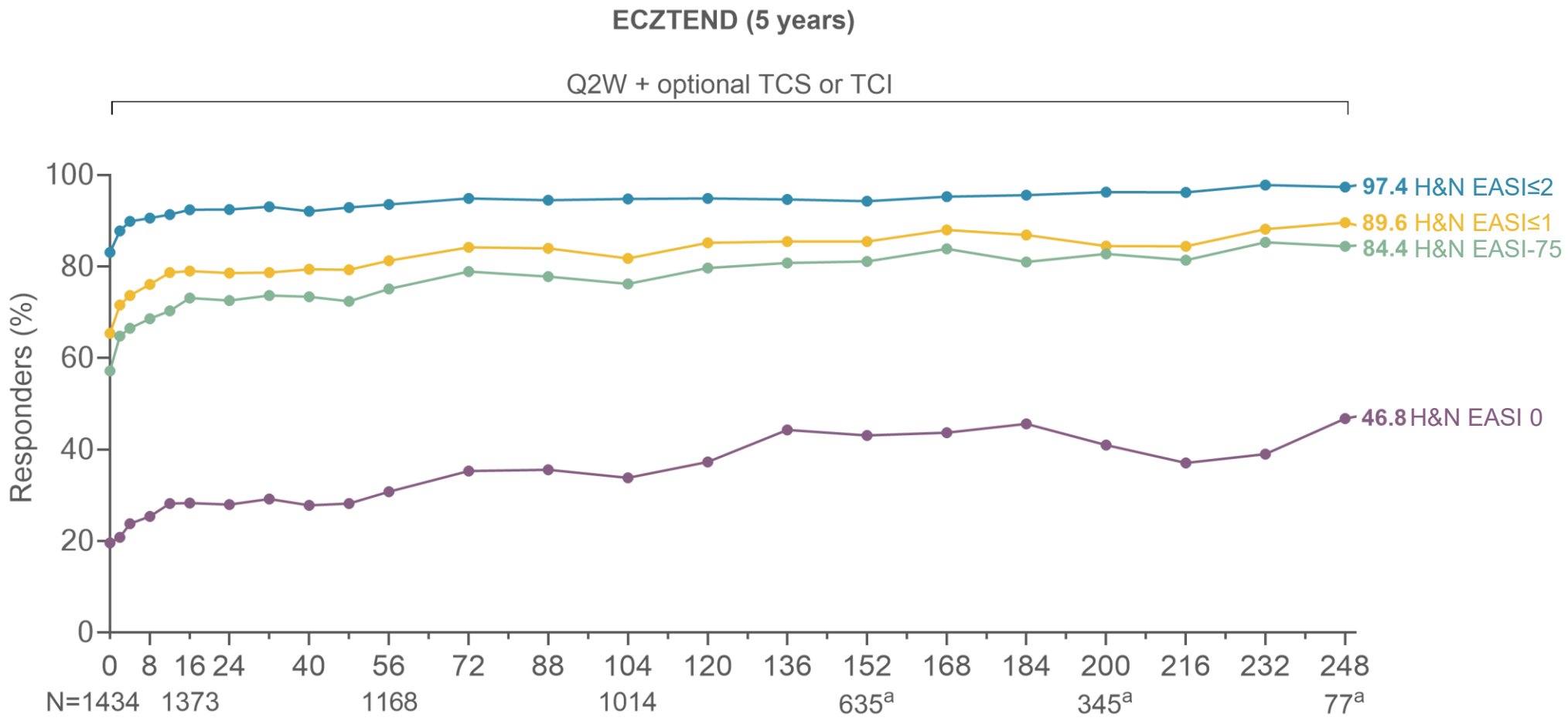
[a]Study duration varied based on patients' consent to the amendment to prolong the study to 5 years and the country of enrollment.
BL, baseline; EASI, Eczema Area and Severity Index; H&N, head and neck; H&N EASI, EASI subscore for head and neck region; IQR, interquartile range; LOCF, last observation carried forward; n, number of patients with recorded observation; PT, patient.

Improvements in H&N EASI were comparable to other body regions



[a]Standardized EASI or EASI subscore was calculated using median divided by respective maximum scale range (multiplied by 100) [b]Study duration varied based on patients' consent to the amendment to prolong the study to 5 years and the country of enrollment.
BL, baseline; EASI, Eczema Area and Severity Index; H&N, head and neck; H&N EASI, EASI subscore for head and neck region; LL, lower limb; n, number of patients with observed data at the visit analyzed; PT, patient; Q2W, every 2 weeks; TCI, topical calcineurin inhibitors; TCS, topical corticosteroids; TOT, total; TR, trunk; UL, upper limb.

Proportion of patients maintaining EASI-75, EASI ≤1, EASI ≤2, and EASI 0 in subgroup of patients with H&N EASI ≥1 at parent trial baseline



[a]Study duration varied based on patients' consent to the amendment to prolong the study to 5 years and the country of enrollment.
EASI, Eczema Area and Severity Index; H&N, head and neck; H&N EASI, EASI subscore for head and neck region; EASI-75, ≥75% improvement from baseline; N, number of patients in indicated treatment set; Q2W, every 2 weeks; TCI, topical calcineurin inhibitors; TCS, topical corticosteroids.

Conclusions

- Tralokinumab provided sustained improvements of H&N AD in patients (≥12 years) continuing treatment for up to 5 years in the ECZTEND long-term extension trial
- Improvements observed for H&N EASI sub-scores were comparable to those observed for other body regions
- Combined, these results demonstrate that tralokinumab is an efficacious long-term option for AD patients with H&N involvement

AD, atopic dermatitis; EASI, Eczema Area and Severity Index; H&N, head and neck; H&N EASI, EASI subscore for head and neck region.

Thank you for listening

Disclosures

- **Andreas Wollenberg** has served as an advisor or paid speaker for, or participated in clinical trials (with honoraria paid to the institution) sponsored by: AbbVie, Aileens, Almirall, Amgen, Apogee, Beiersdorf, Bioderma, Bioproject, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Chugai, DKSH, Eli Lilly, Galapagos, Galderma, Glenmark, GSK, Hans Karrer, Hexal, Incyte, Janssen-Cilag, Kyowa Kirin, LEO Pharma, L'Oreal, Maruho, MedImmune, MSD, Mylan, MSD, Nektar, Novartis, Pfizer, Pierre Fabre, Regeneron, Sandoz, Santen, Sanofi, and UCB.
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- **Chang Ook Park** is an investigator for Sanofi, Pfizer, Galderma, Eli Lilly, LEO Pharma, Amgen, AstraZeneca, GSK, Kiniksa Pharmaceuticals, and Teva Pharmaceuticals.
- **Simone Ribero** has received research grants, personal fees, or nonfinancial support from AbbVie, Almirall, BMS, Galderma, LEO Pharma, Lilly, L'Oreal, Novartis, Pfizer, Pierre Fabre, and Sanofi.
- **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.
- **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.
- **Julien Seneschal** has served as an advisor or paid speaker for or participated in clinical trials (with honoraria paid to the institution) sponsored by: AbbVie, Almirall, Amgen, Bristol Myers Squibb, Eli Lilly, Galderma, Janssen-Cilag, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Sanofi-Aventis and UCB.
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- **Andrew Blauvelt** has served as a speaker (received honoraria) for Eli Lilly and Company and UCB, has served as a scientific adviser (received honoraria) for AbbVie, Almirall, Alumis, Amgen, Anaptysbio, Apogee, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Galderma, GlaxoSmithKline, Incyte, IQVIA, Janssen, LEO Pharma, Lipidio, Merck, Novartis, Oruka, Paragon, Pfizer, Regeneron, Sanofi, Spherix Global Insights, Sun Pharma, Takeda, UCB Pharma, and Union, has acted as a clinical study investigator (institution has received clinical study funds) for AbbVie, Acelyrin, Almirall, Alumis, Amgen, Arcutis, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, Eli Lilly and Company, Galderma, Incyte, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Takeda, and UCB Pharma, and owns stock in Lipidio and Oruka.

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