Real-world effectiveness of up to 12-months' tralokinumab treatment in adults with atopic dermatitis who previously discontinued dupilumab or Janus kinase inhibitors

April W Armstrong[1], Adrian Rodriguez[2], Jose Juan Pereyra Rodriguez[3,4], Ahmed Ameen[5], Elena Pezzolo[6], Jennifer Beecker[7], Teodora Festini[8], Frank Vinther[8], Ida Vittrup[8], Diamant Thaçi[9]

[1]University of California Los Angeles, David Geffen School of Medicine, Division of Dermatology, Department of Medicine, Los Angeles, California, United States; [2]Nashville Skin, Nashville, Tennessee, United States; [3]Virgen del Rocio University Hospital, Department of Dermatology, Sevilla, Spain; [4]University of Sevilla, Department of Medicine, School of Medicine, Sevilla, Spain; [5]NMC Specialty Hospital, Abu Dhabi, United Arab Emirates; [6]Department of Dermatology, San Bortolo Hospital, Vicenza, Italy; [7]The Ottawa Hospital Research Institute, Division of Dermatology, The Ottawa Hospital, Ottawa, Ontario, Canada; [8]LEO Pharma A/S, Ballerup, Denmark; [9]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany.

Objectives

- The TRACE study assesses the real-world effectiveness and safety of up to 12-months of tralokinumab treatment in patients with atopic dermatitis (AD)
  - Here we evaluate the effectiveness of tralokinumab in AD patients previously treated with dupilumab or Janus kinase inhibitors (JAKi)

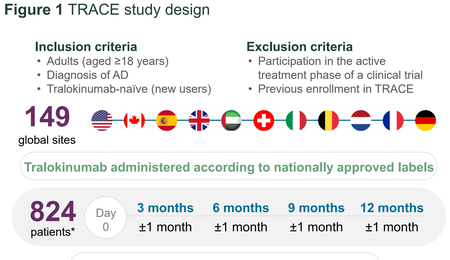
Background

- AD is a chronic and burdensome skin disease which significantly impacts patients' quality of life[1,2]
- Tralokinumab is a monoclonal antibody targeting interleukin-13, indicated for the treatment of moderate-to-severe AD, and has demonstrated efficacy and tolerability in Phase 3 clinical trials[3-5]

Methods

- TRACE is a prospective, non-interventional, international, single-cohort study of 835 adults with AD who were prescribed tralokinumab according to the national approved label at treating physician's discretion (**Figure 1**)
- 824 comprised the full analysis set; 182 patients were previously treated with dupilumab and 51 were previously treated with JAKi
  - The most common reasons for discontinuing prior dupilumab or JAKi therapy were loss- or lack-of efficacy, and adverse events (**Table 2**)

Figure 1 TRACE study design



*:835 patients were enrolled, of which 824 were included in the FAS and 825 in the SAF.

- Effectiveness outcomes were assessed per routine clinical practice. Two composite responder (CR) definitions were used:
  - CR1: Patients achieving IGA 0/1 **or** EASI-75 **or** SCORAD <10
  - CR2: Patients achieving IGA 0/1 **or** EASI ≤7 **or** SCORAD <10

Table 1 Baseline disease characteristics

	All patients N=824	Patients previously treated with dupilumab N=182	Patients previously treated with JAK inhibitors N= 51
Mean age, years (SD)	44.1 (17.9)	46.8 (17.8)	44.3 (16.2)
Female sex, n (%)	392 (47.6)	97 (53.3)	27 (52.9)
Race			
White, n (%)	624 (75.7)	132 (72.5)	34 (66.7)
Asian, n (%)	44 (5.3)	11 (6.0)	5 (9.8)
Black or African American, n (%)	37 (4.5)	10 (5.5)	2 (3.9)
Unknown*, n (%)	71 (8.6)	19 (10.4)	7 (13.7)
Other†, n (%)	48 (5.8)	10 (5.5)	3 (5.9)
Duration of AD, mean (SD), years	18.8 (17.7)	23.2 (20.0)	23.1 (18.4)

*Includes unknown, not available and not reported values. †Includes American Indian/Alaska Native, Native Hawaiian/Pacific Islander, multiple races, and other.

Table 2 Reasons for discontinuation of prior treatments*

Total reasons for discontinuation of dupilumab, n (%)	N=191
Adverse event	59 (30.9)
Loss of effect	52 (27.2)
Lack of effect	48 (25.1)
Other	18 (9.4)
Intolerance	9 (4.7)
Not covered by insurance	4 (2.1)
Out of pocket cost too high	1 (0.5)
Total reasons for discontinuation of JAK inhibitors, n (%)	**N=65**
Adverse event	13 (20.0)
Lack of effect	20 (30.8)
Loss of effect	16 (24.6)
Other	11 (16.9)
Intolerance	2 (3.1)
Not applicable	2 (3.1)
Not covered by insurance	1 (1.5)

*Some patients reported more than 1 reason for discontinuation of prior treatment with dupilumab or JAK inhibitors

Abbreviations AD, atopic dermatitis; CI, Confidence interval; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EASI-75, at least 75% reduction in EASI score from baseline; FAS, full analysis set; IGA, Investigator's Global Assessment; JAK, Janus kinase; n, number of subjects with observation; N, number of subjects in analysis set (or subset); N/A, not applicable; NRS, numeric rating scale; SAF, safety analysis set; SCORAD, Scoring Atopic Dermatitis; SD, standard deviation.

Acknowledgements This analysis was sponsored by LEO Pharma A/S, Ballerup, Denmark. Medical writing support was provided provided by Casper Kornbech Larsen (employee at LEO Pharma A/S) and Hanne Fejer Andersen (independent consultant funded by LEO Pharma A/S).

References 1. Feldman SR, et al. *J Dermatolog Treat.* 2024;35(1):2345739; **2.** Ameen M, et al. *Acta Derm Venereol.* 2024;104:adv24339; **3.** Bieber T. *Allergy.* 2020;75(1):54-62; **4.** Wollenberg A, Blauvelt A, Guttan-Yassky E, et al. *Br J Dermatol.* 2021;184(3):437-449; **5.** Simpson EL, Blauvelt A, Silverberg JI, et al. *Am J Clin Dermatol.* 2024;25:139-148.

Disclosures **April W. Armstrong** has served as a research investigator and/or scientific advisor to AbbVie, Almirall, Arcutis Biotherapeutics, ASLAN, Beiersdorf, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, Dermira, EPI, Incyte Corporation, Janssen, LEO Pharma A/S, Lilly, Modmed, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, Sun Pharma and UCB. **Adrian Rodriguez** is an investigator and consultant/advisor or speaker for: Abbvie, Arcutis, Bristol Myers Squibb, Eli Lilly, Incyte, Janssen, Leo Pharma, Novartis, Sun, and UCB. **Jose Juan Pereyra Rodriguez** has received honoraria for research from Novartis, Abbvie, Galderma, LEO Pharma, Lilly, and Sanofi, and for lecturing and other financial benefit from Abbvie, Almirall, Galderma, Janssen, Gebro-Pharma, LEO Pharma Novartis, Lilly, Novartis, Pfizer, Sanofi, and UCB. **Ahmed Ameen** has been a speaker, advisor, and/or investigator for AbbVie, Bayer, Boehringer Ingelheim, Ego Pharmaceuticals, Galderma, Jamjoom Pharma, Janssen, LEO Pharma A/S, Lilly, Novartis, Organon, Pfizer, Sanofi, and Viatris. **Elena Pezzolo** has been consultant, clinical trial investigator and speaker for LEO Pharma, Abbvie, Pfizer, Novartis, Sanofi Genzyme, Galderma, Almirall, Boehringer Ingelheim, and Janssen. **Jennifer Beecker** has served as an investigator, speaker, advisor/consultant for and/or received grants/honoraria from AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert, Galderma, Eli Lilly, Incyte, Janssen, Johnson and Johnson, LEO Pharma, L'Oréal Group, Novartis, Pfizer, Reistone, Sanofi Genzyme, and UCB. **Teodora Festini, Frank Vinther & Ida Vittrup** are shareholders and employees of LEO Pharma A/S. **Diamant Thaçi** has served as an investigator and/or consultant/adviser for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Celltrion, Eli Lilly, Galderma, Incyte, Johnson&Johnson, LEO Pharma, L'Oreal, Meiji, New Bridge, Novartis, Regeneron, Pfizer, Sanofi, Sun Pharma, Takeda, Target-RWE, UCB, & Vichy. He has received grants from AbbVie and LEO Pharma.

Presented at the 45th Annual Fall Clinical Dermatology Conference, 23 – 26 October 2025

Scan to download a copy of this poster

Copies of this poster and its content, obtained through this QR code, are for personal use only and may not be reproduced without written permission from the authors

Conclusions

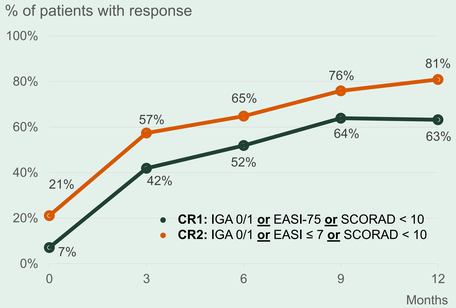
- Tralokinumab treatment for up to 12 months was effective in a real-world setting in patients previously treated with dupilumab or JAK inhibitors, with clinical responses consistent with the overall TRACE population
- Improvements were observed across measures of AD symptoms, itch, and health-related quality of life
- These finding suggest that tralokinumab is an effective treatment option for AD in patients who have previously discontinued treatment with dupilumab or JAK inhibitors

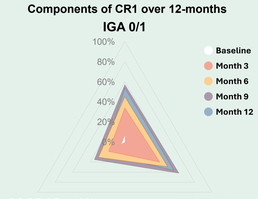
Results

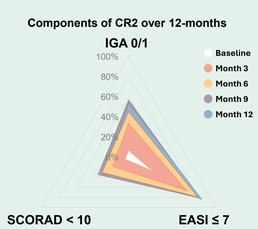
Effectiveness of tralokinumab treatment for 12 months

- The proportion of patients with a CR increased rapidly from baseline to month 12 in both patients previously treated with dupilumab (**Figure 2)** and patients previously treated with JAKi (**Figure 3**)
  - CR was similar among dupilumab- and JAKi-experienced patients and the FAS, where 86% achieved CR definition 1 and 79% achieved CR definition 2 by month 12
- Substantial improvements in AD symptoms, itch, and health-related quality of life were observed with 12 months of treatment in both patients previously treated with dupilumab (**Table 3**) and patients previously treated with JAKi (**Table 4**)

Figure 2 Effectiveness of up to 12-months tralokinumab in patients previously treated with dupilumab



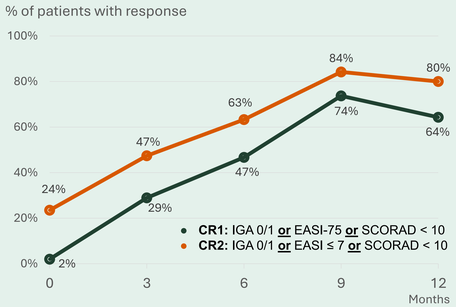


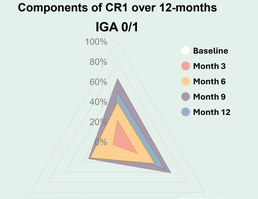


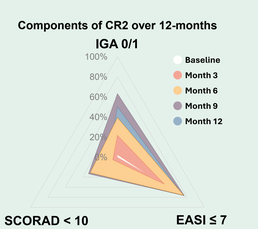
	Baseline	3 months	6 months	9 months	12 months
CR1, n/N	12/169	57/136	56/108	53/83	43/68
CR2 n/N	38/180	78/136	70/108	63/83	55/68

Denominator for the proportions, N is patients with at least one response assessment at the given visit. Note that EASI-75 is 0 at baseline.

Figure 3 Effectiveness of up to 12-months tralokinumab in patients previously treated with JAKi







	Baseline	3 months	6 months	9 months	12 months
CR1, n/N	1/50	11/38	14/40	14/19	9/14
CR2, n/N	12/51	18/38	19/30	16/19	12/15

Denominator for the proportions, N, is patients with at least one response assessment at the given visit. Note that EASI-75 is 0 at baseline.

Table 3 Patient-reported outcomes among dupilumab-experienced patients receiving up to 12-months tralokinumab therapy

	Mean DLQI score	DLQI ≤ 5 Proportion (95%CI)	Mean Peak pruritus NRS score	Peak pruritus NRS ≤ 4 Proportion (95%CI)
Baseline	n=92 10.9	n=92 29.3 (20.3 - 39.8)	n=116 5.6	n=116 35.3 (26.7 - 44.8)
3 months	n=43 6.6	n=43 48.8 (33.3 - 64.5)	n=55 4.6	n=55 52.7 (38.8 - 66.3)
6 months	n=37 6.4	n=37 67.6 (50.2 - 82.0)	n=46 3.9	n=46 60.9 (45.4 - 74.9)
9 months	n=29 6.7	n=29 58.6 (38.9 - 76.5)	n=34 3.8	n=34 64.7 (46.5 - 80.3)
12 months	n=25 6.3	n=25 56.0 (34.9 - 75.6)	n=28 4.0	n=28 60.7 (40.6 - 78.5)

Table 4 Patient-reported outcomes among JAKi-experienced patients receiving up to 12-months tralokinumab therapy

	Mean DLQI score	DLQI ≤ 5 Proportion (95%CI)	Mean Peak pruritus NRS score	Peak pruritus NRS ≤ 4 Proportion (95%CI)
Baseline	n=28 11.1	n=28 21.4 (8.3 - 41.0)	n=36 6.6	n=36 22.2 (10.1 - 39.2)
3 months	n=15 7.2	n=15 66.7 (38.4 - 88.2)	n=19 5.1	n=19 47.4 (24.4 - 71.1)
6 months	n=13 6.3	n=13 61.5 (31.6 - 86.1)	n=15 3.8	n=15 66.7 (38.4 - 88.2)
9 months	n=10 6.9	n=10 40.0 (12.2 - 73.8)	n=11 4.0	n=11 54.5 (23.4 - 83.3)
12 months	n=6 7.0	n=6 50.0 (11.8 - 88.2)	n=7 4.0	n=7 57.1 (18.4 - 90.1)