Posters

LEBRIKIZUMAB FOR PAEDIATRIC PATIENTS AGED ≥6 MONTHS WITH MODERATE-TO-SEVERE AD: PHASE 3 ADORABLE-1 WEEK-16 RESULTS

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Background and Objectives. To evaluate the efficacy and safety of lebrikizumab compared to placebo (PBO) in patients 6 months to <18 years of age with moderate-to-severe atopic dermatitis (AD) in the randomised, double-blind, PBO-controlled, Phase 3 ADorable-1 study (NCT05559359). AD is the most prevalent systemic chronic inflammatory skin condition in children, affecting 15–20% worldwide1. There is a significant unmet need due to limited treatment options: only one biologic option is approved for use in patients as young as 6 months of age with moderate-to-severe AD. Lebrikizumab binds interleukin-13 with high binding affinity and slow dissociation rate. Interleukin-13 is a key driver of AD pathogenesis. Lebrikizumab is currently approved for adolescent patients aged ≥12 years, weighing ≥40 kg with moderate-to-severe AD.

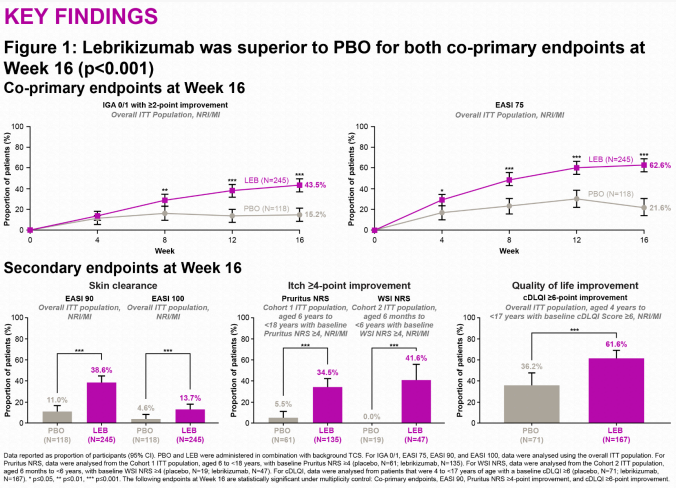
Methods. Key inclusion criteria. Age ≥6 months to <18 years. Weight minimum ≥6 kg for all patients, and <40 kg for patients aged ≥12 to <18 years. EASI score ≥16. IGA score ≥3 (on a 0–4 scale). ≥10% body surface area (BSA) involvement. Diagnosis of AD per American Academy of Dermatology criteria, with duration requirements tiered by age: – ≥12 months if the participant was ≥6 years old – ≥6 months if 2 to <6 years old – ≥3 months if 6 months to <2 years old Key exclusion criteria. Prior treatments before baseline: – Dupilumab within 8 weeks (enrollment of patients with prior dupilumab use was capped at <20% of the study population) – Other biologics within 5 half-lives (if known) or 16 weeks, whichever is longer TCS standardisation. Two weeks before the baseline visit, a standardised topical corticosteroid (TCS) treatment was initiated for all patients and continued through the end of the study. TCS use was tapered upon lesion clearance (IGA ≤2 → 3×/week; IGA 0 → stop), alongside daily non-medicated emollient use throughout the study Rescue medication. Rescue medication included high or ultra-high-potency TCS, and any systemic AD treatment Analysis populations. Efficacy analyses used the overall Intent-to-Treat (ITT) population. Safety analyses used the Overall Safety population Statistical analyses. Treatment comparisons used the Cochran-Mantel-Haenszel test stratified by geographic region, age group at first visit and disease severity. Primary method of handling missing efficacy data (non-responder imputation/multiple imputation [NRI/MI]): – Patients who received rescue medication were analysed as non-responders – For patients who discontinued treatment for any reason, observed data after treatment discontinuation were used; Markov chain Monte Carlo multiple imputation was used to handle the remaining missing data. The family-wise type 1 error is controlled at a 2-sided level of 0.05 using the graphical multiple testing strategy. The overall ITT population is defined as all randomised patients from Cohort 1 and all randomised patients from Cohort 2 who either complete or have an opportunity to complete treatment through Week 16 at the time of the data cut. The Overall Safety population is defined as all randomised patients from Cohorts 1 and 2 who received ≥1 dose of study treatment and who either complete or have an opportunity to complete treatment through Week 16.

Conclusions. In the Phase 3 ADorable-1 study, lebrikizumab demonstrated statistically significant and clinically meaningful efficacy versus PBO, meeting both co-primary endpoints of Investigator's Global Assessment (IGA) 0/1 with ≥2-point improvement and Eczema Area And Severity Index (EASI) 75 at Week 16 in patients aged 6 months to <18 years with moderate-to-severe AD. Treatment with lebrikizumab resulted in consistent improvements in key measures of disease severity and symptoms (skin clearance, itch relief and quality of life). The safety profile of lebrikizumab in ADorable-1 was consistent with prior studies in adult and adolescent patients with moderate-to-severe AD, and no new safety findings were identified over 16 weeks of treatment. These results provide evidence supporting interleukin-13-targeted therapy as a novel treatment for a broad paediatric

population.

KEY FINDINGS

Figure 1: Lebrikizumab was superior to PBO for both co-primary endpoints at Week 16 (p<0.001)



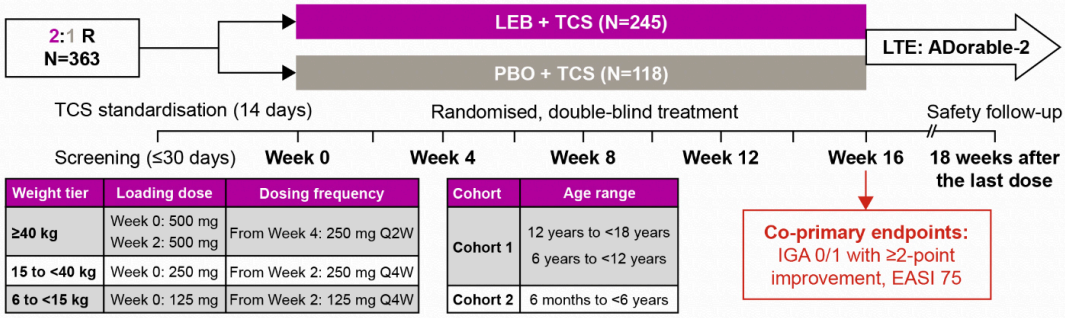
Data reported as proportion of participants (95% CI). PBO and LEB were administered in combination with background TCS. For IGA 0/1, EASI 75, EASI 90, and EASI 100, data were analysed using the overall ITT population. For Pruritus NRS, data were analysed from the Cohort 1 ITT population, aged 6 to <18 years, with baseline Pruritus NRS ≥4 (placebo, N=61; lebrikizumab, N=135). For WSI NRS, data were analysed from the Cohort 2 ITT population, aged 6 months to <6 years, with baseline WSI NRS ≥4 (placebo, N=19; lebrikizumab, N=47). For cDLQI, data were analysed from patients that were 4 to <17 years of age with a baseline cDLQI ≥6 (placebo, N=71; lebrikizumab, N=167). * p≤0.05, ** p≤0.01, *** p≤0.001. The following endpoints at Week 16 are statistically significant under multiplicity control: Co-primary endpoints, EASI 90, Pruritus NRS ≥4-point improvement, and cDLQI ≥6-point improvement.

Table 1: Adverse events

All data are n (%)	PBO + TCS N=118	LEB + TCS N=245
TEAE	70 (59.3)	140 (57.1)
TEAE by severity[a]		
Mild	35 (29.7)	91 (37.1)
Moderate	32 (27.1)	46 (18.8)
Severe	3 (2.5)	3 (1.2)
Death	0	0
Serious AE	3 (2.5)	3 (1.2)
TEAE related to study treatment	9 (7.6)	32 (13.1)
Discontinuation from study due to AE (including death)	0	0
AEs of Special Interest		
Eosinophilia		†[1]
Infections	50 (42.4)	96 (39.2)
Herpes infections (oral herpes and eczema herpeticum)[‡]	1 (0.8)	1 (0.4)
Parasitic infections	0	0
Skin infections	10 (8.5)	6 (2.4)
Conjunctivitis cluster[§]	6 (5.1)	18 (7.3)
Keratitis cluster	0	0
Injection-site reactions[¶]	3 (2.5)	5 (2.0)

Data were analysed using the Overall Safety population. [a]Patients with multiple occurrences of the same event are counted under the highest severity. [b]ADorable-1 is an ongoing trial; study grouping and percentages were removed to prevent unblinding when there is a single event reported. There was one reported occurrence of eosinophilia. Eosinophil-related AEs are defined using specific MedDRA preferred terms specified in the PSAP. [c]Herpes infections events were non-serious and mild, and did not lead to discontinuation. [d]Conjunctivitis events were all non-serious, mild or moderate in severity, and no event led to discontinuation. Conjunctivitis cluster includes the PTs: Conjunctivitis, Conjunctivitis allergic, Conjunctivitis bacterial, Conjunctivitis viral, and Giant papillary conjunctivitis. [e]In both treatment groups, all events were mild, resolved, and were reported as Injection site reaction (PT). No other PT in the HLT was reported, such as Injection site erythema (PT), Injection site haematoma (PT), Injection site pain (PT), or Injection site pruritus (PT). Note: The Overall Safety population is defined as all randomised patients from Cohorts 1 and 2 who received ≥1 dose of study treatment and who either complete or have an opportunity to complete treatment through Week 16. A TEAE is defined as an event that first occurred or worsened in severity after baseline and on or prior to the date of the last visit within the specified treatment period. A Serious AE is categorised as death, life-threatening, disability or permanent damage, hospitalisation (initial or prolonged), congenital anomaly / birth defect, requires intervention, other serious important medical events. Serious AE preferred terms: PBO + TCS: Asthmatic crisis (1); Atopic dermatitis exacerbation (1), Periorbital oedema (1); LEB + TCS: Pneumonia (1), Synovitis (1), Abscess limb + Joint abscess + Otitis media (1). None of the Serious AEs led to treatment discontinuation. Infections are defined using the MedDRA preferred terms from the Infections and Infestations System Organ Class; the majority of infection events were mild or moderate in severity. Keratitis cluster includes the PTs: Allergic keratitis, Atopic keratoconjunctivitis, Keratitis, Ulcerative keratitis, and Vernal keratoconjunctivitis.

Figure 2: Study design



Weight tier	Loading dose	Dosing frequency
≥40 kg	Week 0: 500 mg Week 2: 500 mg	From Week 4: 250 mg Q2W
15 to <40 kg	Week 0: 250 mg	From Week 2: 250 mg Q4W
6 to <15 kg	Week 0: 125 mg	From Week 2: 125 mg Q4W

Cohort	Age range
Cohort 1	12 years to <18 years 6 years to <12 years
Cohort 2	6 months to <6 years

All participants were instructed to use TCS (low- or mid-potency) starting 2 weeks before the baseline visit. Region-specific medical coding guidelines were not applied; WHODrug Version: WHO Drug Global B3, Sep2025. Participants who complete the study through Week 16 will be eligible for enrollment in a long-term extension study (ADorable-2) to assess the long-term safety and efficacy of lebrikizumab. Safety follow-up assessments will be conducted 18 weeks after the last dose for those participants who discontinue the study early or those who complete the study through Week 16 but do not enroll in the long-term extension study.

Table 2: Baseline demographics

Data are mean (SD), unless otherwise indicated	PBO + TCS N=118	LEB + TCS N=245
Female, n (%)	64 (54.2)	116 (47.3)
Age (years)[a]	7.6 (3.07)	7.7 (3.32)
Age category, n (%)		
6 months to <2 years	4 (3.4)	13 (5.3)
2 to <6 years	22 (18.6)	48 (19.6)
6 to <12 years	82 (69.5)	165 (67.3)
12 to <18 years	10 (8.5)	19 (7.8)
BMI (kg/m²)	18.3 (3.8)	18.0 (3.3)
Weight category[b], n (%)		
6 to <15 kg	9 (7.6)	24 (9.8)
15 to <40 kg	87 (73.7)	181 (73.9)
≥40 kg	22 (18.6)	40 (16.3)
Race, n (%)		
White	71 (60.2)	144 (58.8)
Asian	32 (27.1)	63 (25.7)
Black/African American	6 (5.1)	17 (6.9)
Native Hawaiian or Other Pacific Islander	1 (0.8)	1 (0.4)
American Indian or Alaska Native	3 (2.5)	12 (4.9)
Multiple	4 (3.4)	4 (1.6)
Unreported	1 (0.8)	4 (1.6)
Geographic region, n (%)		
United States	18 (15.3)	42 (17.1)
Europe	23 (19.5)	45 (18.4)
Rest of world*	77 (65.3)	158 (64.5)

Data from overall ITT population. [a]Age calculated at date of first visit (screening). [b]Weight category was based on the patient's weight at Visit 3 (baseline). *Rest of world †or pooled study population includes Latin America (n=135 [37.2%]), followed by Asia (n=79 [21.8%]), Australia (n=13 [3.6%]), and Canada (n=8 [2.2%]).

Table 3: Rescue medication use

All data are n (%)	PBO + TCS N=118	LEB + TCS N=245
Patients with ≥1 rescue medication[a]	14 (11.9)	8 (3.3)
High-potency TCS	9 (7.6)	7 (2.9)
Systemic therapy	5 (4.2)	1 (0.4)
Systemic CS	5 (4.2)	1 (0.4)
Immunosupressant	0	0
Biologics	0	0
Phototherapy or Photochemotherapy	0	0

Data from overall ITT population. [a]Rescue medication for AD in the treatment period is defined as the use of any high or ultra-high-potency TCS or any systemic medication. Note: Rescue treatment with high-potency TCS was permitted for patients with an IGA score of 4 or intolerable symptoms, per the investigator's judgment. Systemic corticosteroids or systemic immunosuppressants used as rescue medication required permanent discontinuation of study intervention.

Table 4: Baseline disease characteristics

	Data are mean (SD), unless otherwise indicated	PBO + TCS N=118	LEB + TCS N=245
Physician-reported outcomes	**Age at AD onset (years)**[a]	1.4 (2.19)	1.8 (2.55)
	IGA, n (%)		
	3	90 (76.3)	182 (74.6)
	4	28 (23.7)	62 (25.4)
	EASI	28.9 (10.61)	28.3 (9.94)
	BSA	47.0 (19.93)	45.1 (18.35)
Patient-reported outcomes	**Pruritus NRS (patients ≥6 years)**	5.8 (2.49)	6.4 (2.19)
	Score ≥4, n (%)	61 (73.5)	135 (85.4)
	WSI NRS (patients <6 years)	6.9 (1.78)	6.9 (2.08)
	Score ≥4, n (%)	19 (90.5)	47 (92.2)
	cDLQI (patients 4 to <17 years)	10.6 (6.83)	10.9 (6.41)
	Score ≥6, n (%)	71 (68.9)	167 (78.8)
	PROMIS Sleep disturbance	66 (10.8)	66.2 (9.7)
	PROMIS Sleep-related impairment	59.3 (11.8)	56.9 (11.5)
Prior treatment for AD management	**TCS**	114 (96.6)	236 (96.3)
	TCI	57 (48.3)	113 (46.1)
	Topical PDE4i	7 (5.9)	19 (7.8)
	Janus kinase inhibitors[b]	7 (5.9)	15 (6.1)
	Prior systemic treatment use, n (%)	70 (59.3)	132 (53.9)
	Systemic CS	41 (34.7)	75 (30.6)
	Dupilumab	13 (11.0)	30 (12.2)
	Cyclosporine	14 (11.9)	23 (9.4)
	Mycophenolate-mofetil	0	0
	IFN-γ	0	0
	Azathioprine	0	0
	Methotrexate	14 (11.9)	15 (6.1)
	Tralokinumab	0	0
	Phototherapy	11 (9.3)	21 (8.6)
	Other biologics	1 (0.8)	3 (1.2)
	Other non-biologic medication/treatment	20 (16.9)	39 (15.9)

Data from overall ITT population. [a]Calculated as the difference between date of onset of AD and date of birth. [b]Includes both topical and systemic Janus kinase inhibitors.

Abbreviations: *AD=atopic dermatitis; AE=adverse events; BMI=body mass index; BSA=body surface area; cDLQI=children's Dermatology Life Quality Index; CI=confidence interval; CS=corticosteroid; EASI=Eczema Area and Severity Index; EASI 100=100% improvement from baseline in EASI; EASI 75=≥75% improvement from baseline in EASI; EASI 90=≥90% improvement from baseline in EASI; HLT=high level term; IGA=Investigator's Global Assessment; IGA 0/1= IGA score of 0 or 1; IFN=interferon; ITT=intent-to-treat; LEB=lebrikizumab; LTE=long-term extension; MedDRA=Medical Dictionary for Regulatory Activities; MI=multiple imputation; N=number of patients in the analysis population; n=number of patients in the specified category; NRI=non-responder imputation; NRS=numeric rating scale; PBO=placebo; PDE4=phosphodiesterase type 4 inhibitor; PROMIS=patient-reported outcomes measurement information system; PSAP=program safety analysis plan; PT=preferred term; Q2W=every 2 weeks; Q4W=every 4 weeks; R, randomisation; SD=standard deviation; TCI=topical calcineurin inhibitor; TCS=topical corticosteroid; TEAE=treatment-emergent adverse event; WSI=worst scratching/itching.* **Acknowledgements:** The authors would like to thank Emily Dennis, PhD, an employee of Eli Lilly and Company, for providing writing and editorial contributions for the original SPD 2026 submission. The authors also thank Megan Evans, BSc, Costello Medical, London, UK, for providing editorial assistance, and the Costello Medical Creative team for design support for the resubmission to ADOI 2026, in accordance with Good Publication Practice (GPP) 2022 guidelines. **References:** 1. Weidinger S, Beck LA, Bieber T, Kabashima K, Irvine AD. Atopic dermatitis. Nat Rev Dis Primers. 2018;4:1. **Disclosures: LS** has been principal investigator in clinical trials sponsored by and/or a member of advisory board or speaker for AbbVie, Almirall, Bristol Meyer Squibb, Celgene, Eli Lilly, Janssen, Leo Pharma, Novartis and Sanofi Genzyme. **LE** has served as a consultant, adviser or investigator for AbbVie, Abeona, Acrotech, Almirall, Amgen, Apogee, Arcutis, Attovia, Bristol Myers Squibb, Caste Biosciences, Chiesi, Corevitas, Dermavant, Formation Bio, Forte, Galderma, Incyte, Janssen, Kennue, Kymera, Krystal, LEO, Lilly, Novartis, OrthoDerm, Pfizer, Regeneron, Sanofi Genzyme, Takeda, Target RWE, T-Rex, UCB and Vernica. **JO** reports consulting fees: LEO, Organon; Speakers Bureau: Organon. **VP** has served as an adviser, consultant, speaker, and/or investigator for: AbbVie, Actelion, Amgen, Anaptysbio, Arakez Bio, Arcutis, Arena Pharmaceuticals, Aspen Pharmacare, Bausch Health, BioScript Solutions, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Cipher Pharmaceuticals, Concert Pharmaceuticals, CorEvitas, Dermavant, Dermira, Eli Lilly and Company, Galderma, GSK, Homeocan, Incyte Corporation, Janssen, LEO Pharma, Medexus Pharmaceuticals, Nimbus Lakshmi, Novartis, Pediapharm, Pfizer, RAPT Therapeutics, Regeneron, Restore Biopharma, Sanofi Genzyme, Sun Pharma, Tribute Pharmaceuticals, UCB and Valeant Pharmaceuticals. **CY** has served as a consultant, adviser or investigator for AbbVie, Amgen, Lilly, Novartis, Pfizer, Regeneron, Sanofi. **AT** received lecture fees from AbbVie GK, Eli Lilly Japan K.K., Tanabe Pharma Corporation, Pfizer Japan Inc., Sanofi K.K., Toni Pharmaceutical Co., Ltd., Otsuka Pharmaceutical Co., Ltd, and Maruho Co., Ltd., advisory fees from Pfizer Japan Inc., Eli Lilly Japan K.K., Sanofi K.K., and Maruho Co., Ltd., and research grants not related to the submitted work from Maruho Co., Ltd. **SW** has received consulting fees, honoraria, grant support, and/or lecture fees from AbbVie, Almirall, Apogee, Astria, Boehringer, Eli Lilly, Galderma, GSK, Leo Pharma, Pfizer, Regeneron Pharmaceuticals, Sanofi and UCB. **CF** reports compensation from the British Journal of Dermatology (re-viewer and Section Editor) and EuroGuiDerm (guidelines lead) as well as Almirall, Apogee, Biodermia, Incyte, Medac, LEO, Pfizer and Sanofi for advisory and educational activities. **ES** has served as an investigator: Arcutis, Castle, Organon, Sun; speaker: Abbvie, Arcutis, Galderma, Incyte, Johnson & Johnson, Lilly, Organon, Pelthos, Pfizer, Sanofi-Regeneron, Verrica; consultant (Ad Boards): Abbvie, Almirall, Alphyn, Arcutis, Boehringer Ingelheim, Castle, Chiesi, Galderma, Incyte, Johnson & Johnson, Leo, Lily, Organon, Pelthos, Pfizer, Sanofi-Regeneron and Verrica. **LM** reports nothing to disclose. **SD, RGL, HE, EP, PS, GG, MP** and **AL** are employees and shareholders of Eli Lilly and Company. **MG** and **YM** are employees of Almirall. **AP** is an investigator for AbbVie, Biomendics, Dermavant, Eli Lilly, Incyte, Johnson & Johnson Innovative Medicine, MoonLake Immunotherapeutics, Quoin, Regeneron, TWI, and UCB; consultant for Abeona, Almirall, Apogee, APR Applied Pharma Res, Arcutis, BioCryst, Boehringer Ingelheim, Chiesi, Gedeon Richter, Johnson & Johnson Innovative Medicine, Kaman, Lilly, L'Oreal, MoonLake Immunotherapeutics, Novartis, Palvella, Pelthos, Pfizer, Quoin, Sanofi and Takeda; data safety monitoring board for AbbVie, Abeona, Biocryst, and Galderma. **Funding.** This study was funded by Eli Lilly and Company. 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