Lebrikizumab Improves Atopic Dermatitis in Adult and Adolescent Patients With Skin of Color: 16-Week Results From the ADmirable Study

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OBJECTIVES

- Results on efficacy and safety outcomes from ADmirable (NCT05372419), the first Phase 3, open-label, 24-week trial of lebrikizumab in adult and adolescent patients with moderate-to-severe AD and skin of color, a historically under-represented patient population, were first reported at AAD 2024[1]
- This analysis reports the 16-week efficacy and safety outcomes, including innovative measures of post-inflammatory hyperpigmentation and hypopigmentation

CONCLUSIONS

- ADmirable is the first clinical trial to report data from patients with moderate-to-severe AD and skin of color (78% Black or African American patients) using novel tools and scales to evaluate signs and symptoms that matter to patients
- Lebrikizumab improved AD signs and symptoms after 16 weeks of treatment
  - The majority of patients achieved 75% or greater improvement in skin clearance and showed improved symptoms of itch and quality of life
- Based on the novel PDCA-Derm™ scale, lebrikizumab improved hypopigmented and hyperpigmented lesions
- Lebrikizumab's safety profile was consistent with that reported in Phase 3 trials[3-6]
  - No SAEs were reported

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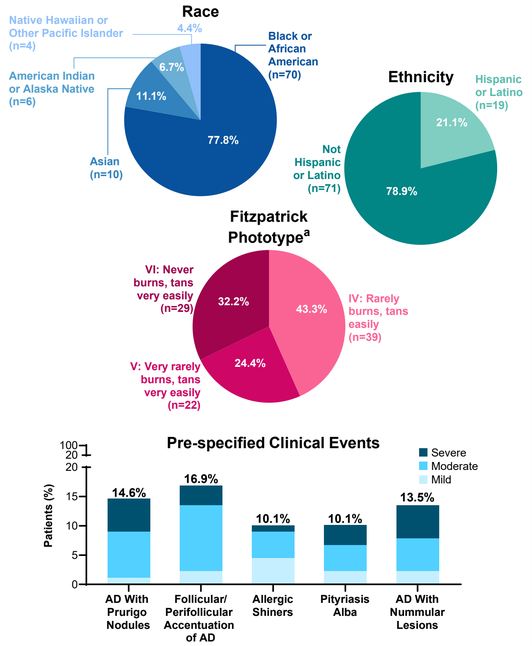
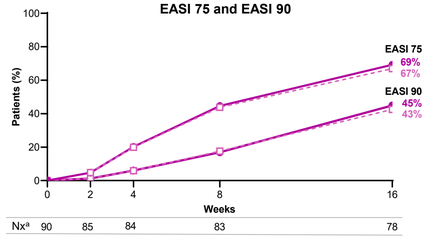
Baseline Demographics and Disease Characteristics

	LEBRI 250 mg Q2W (N=90)
Age, years	40.7 (19.6)
Adult (≥18 years), n (%)	76 (84.4)
Adolescent (≥12 to <18 years), n (%)	14 (15.6)
Female, n (%)	39 (43.3)
BMI, kg/m²	30.1 (7.7)
BMI category, n (%)	
Underweight (<18.5 kg/m²)	3 (3.3)
Normal (≥18.5 and <25 kg/m²)	19 (21.1)
Overweight (≥25 and <30 kg/m²)	30 (33.3)
Obese (≥30 and <40 kg/m²)	26 (28.9)
Extreme obese (≥40 kg/m²)	12 (13.3)
Duration since AD onset, years	19.7 (16.1)
IGA[b]	
3 (Moderate), n (%)	62 (68.9)
4 (Severe), n (%)	27 (30.0)
EASI	26.4 (12.2)
BSA % affected	37.8 (20.5)
POEM	17.3 (6.5)
Pruritus NRS[c]	7.0 (2.2)
≥3, n (%)	73 (93.6)
≥4, n (%)	70 (89.7)
Sleep-Loss scale[c]	2.0 (1.1)
DLQI[d]	13.2 (7.4)
cDLQI[d]	12.2 (8.2)
PO-SCORAD[e]	57.1 (17.8)
PDCA-Derm™[,f]	
Hypopigmented lesion(s), n (%)	16 (17.8)
Hyperpigmented lesion(s), n (%)	52 (57.8)



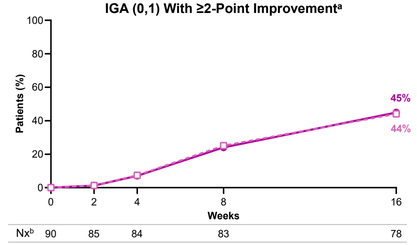
[a]Based on the patient's reported cutaneous reaction to sun exposure; [b]1 patient inadvertently enrolled with IGA<2 and discontinued when discovered they did not meet enrollment criteria; [c]Nx=78; [d]Patients <16 years of age at baseline completed cDLQI [Nx=10]; others completed DLQI [Nx=77]; [e]Nx=87; [f]A scale used to compare post-inflammatory lesions to unaffected, adjacent normal skin.
Notes: Data in table are mean (SD) unless stated otherwise. Percent values for pre-specified clinical events were calculated using 86 as the denominator.

69% of Patients Achieved EASI 75 (Primary Endpoint), and 45% of Patients Achieved EASI 90 at Week 16



[a]As observed.
Notes: NRI/MI analyses are based on all N=90 patients at each timepoint. Patients who discontinued treatment due to lack of efficacy were imputed as non-responders; all other missing data were imputed using MI.

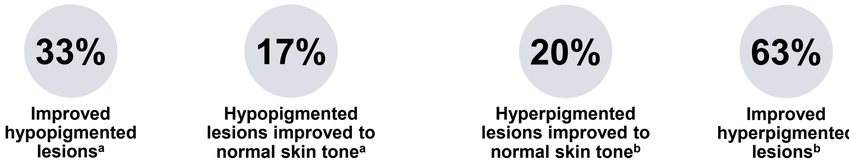
45% of Patients Achieved IGA (0,1) With ≥2-Point Improvement From Baseline at Week 16



[a]ITT population with baseline IGA ≥2; [b]As observed.
Notes: NRI/MI analyses are based on all N=90 patients at each timepoint. Patients who discontinued treatment due to lack of efficacy were imputed as non-responders; all other missing data were imputed using MI.

33% of Patients Showed Improved Hypopigmentation and 63% Showed Improved Hyperpigmentation at Week 16, as measured by PDCA-Derm™

At Week 16:

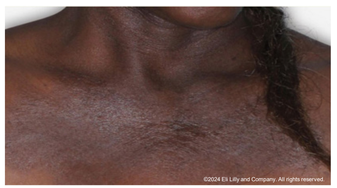


[a]The analysis was performed on patients with a hypopigmentation lesion at baseline and non-missing data at Week 16 (N=12); [b]The analysis was performed on patients with a hyperpigmentation lesion at baseline and non-missing data at Week 16 (N=46).
Notes: For patients with multiple hypopigmented or hyperpigmented lesions at baseline, only the lesion with the most severe score was included in the analysis for each lesion type. In the event of a tie, the lesion reflecting a smaller improvement or worsening in condition from baseline to Week 16 was included.

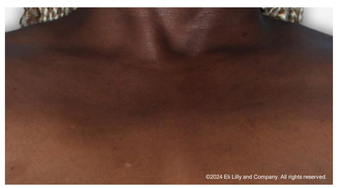
Results

Photographs Showing Improvement in AD With Lebrikizumab in a Patient With Skin of Color

50-year-old Black/African American, non-Hispanic female



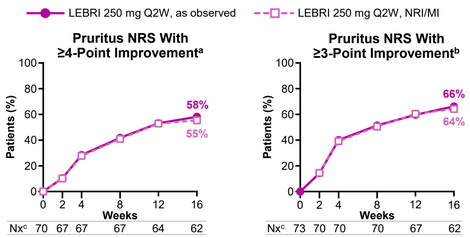
Baseline	
IGA	EASI
3	19.35



Week 16		
IGA	EASI	EASI % CFB
1	2.4	88%

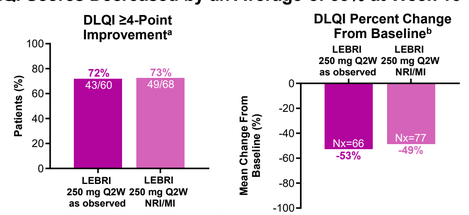
- Information on the ADmirable Study Design, Key Eligibility Criteria, Methods, and Use of Concomitant Topical and Systemic Therapy are described in **Supplemental Materials**

58% of Patients Achieved ≥4-Point Improvement, and 66% Achieved ≥3-Point Improvement in Pruritus NRS at Week 16



[a]ITT population with baseline Pruritus NRS ≥4; [b]ITT population with baseline Pruritus NRS ≥3; [c]As observed. Notes: NRI/MI analyses are based on all N=70 (Pruritus NRS with ≥4-point improvement) or N=73 (Pruritus NRS with ≥3-point improvement) patients at each timepoint. Patients who discontinued treatment due to lack of efficacy were imputed as non-responders; all other missing data were imputed using MI.

72% of Patients Achieved ≥4-Point Improvement in DLQI, and DLQI Scores Decreased by an Average of 53% at Week 16



[a]ITT population with baseline DLQI ≥4; [b]ITT population with baseline DLQI score.
Notes: Data inside bars are n/Nx unless stated otherwise. Participants <16 years of age at baseline completed the cDLQI [Nx=10]; others completed the DLQI [Nx=77]. Patients who discontinued treatment due to lack of efficacy were imputed as non-responders; all other missing data were imputed using MI.

Adverse Events

	LEBRI 250 mg Q2W (N=90)
TEAE[a]	21 (23.3)
Mild	11 (12.2)
Moderate	9 (10.0)
Severe	1 (1.1)
SAE	0
Death	0
TEAE related to study treatment[b]	4 (4.4)
AE leading to treatment discontinuation[b]	0
TEAE within special safety topics	
Infections[c]	6 (6.7)
Skin infections	2 (2.2)
Potential hypersensitivity[d]	1 (1.1)
Injection site reactions	0
Keratitis cluster	0
Conjunctivitis cluster[e]	0
Malignancies[f]	0
AD exacerbation	1 (1.1)
Hepatic events	0

[a]Patients with multiple events with different severity are counted under the highest severity; [b]As assessed by investigator; [c]No cases of herpes infection or helminthic infection were reported; [d]Events that occurred on the day of drug administration and captured using the Hypersensitivity, Angioedema, and Anaphylaxis Standardized MedDRA Queries. The Preferred Term for the potential hypersensitivity event was dermatitis atopic; [e]Defined using the following MedDRA Preferred Terms: conjunctivitis, conjunctivitis allergic, and conjunctivitis bacterial; [f]Includes cases with and without NMSC.
Notes: Data are n (%). Severe TEAE includes back pain.

Abbreviations: *AAD=American Academy of Dermatology; AD=atopic dermatitis; AE=adverse event; BMI=body mass index; BSA=body surface area; cDLQI=Children's DLQI; CFB=change from baseline; DLQI=Dermatology Life Quality Index; EASI=Eczema Area and Severity Index; EASI 75/90=≥75/90% improvement from baseline in EASI; IGA=Investigator's Global Assessment; IGA (0,1)=IGA response of clear or almost clear; ITT=intent-to-treat; IP=investigational product; JAK=Janus kinase; LD=loading dose; LEBRI=lebrikizumab; MedDRA=Medical Dictionary for Regulatory Activities; MI=multiple imputation; NMSC=non-melanoma skin cancer; NRI=non-responder imputation; NRS=Numeric Rating Scale; Nx=number of patients with non-missing values; PDE-4=phosphodiesterase 4; POEM=Patient-Oriented Eczema Measure; PO-SCORAD=Patient-Oriented SCORing of Atopic Dermatitis; Q2W=every 2 weeks; Q4W=every 4 weeks; QoL=quality of life; SAE=severe adverse event; SD=standard deviation; TCI=topical calcineurin inhibitor; TCS=topical corticosteroids; TEAE=treatment-emergent adverse event*

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3. Blauvelt A, et al. *Br J Dermatol*. 2023;188:740-748.
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6. Simpson EL, et al. *JAMA Dermatol*. 2023;159:182-191.

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Almirall, S.A. has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications, including atopic dermatitis, in Europe.
Lilly has exclusive rights for development and commercialization of lebrikizumab in the United States and the rest of the world outside of Europe.

Supplemental Materials
Scan the QR code for additional Methods and Results

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