R389

Lebrikizumab Effectively Treats Moderate-to-Severe Atopic Dermatitis in Adolescent Patients with Atopic Comorbidities

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OBJECTIVE

- To assess lebrikizumab (LEB) efficacy in adolescent patients with moderate-to-severe AD with and without atopic comorbidities from the 52-week Phase 3 open-label trial, ADore (NCT04250350).

CONCLUSION

- Most adolescents with moderate-to-severe AD in ADore had 1 or more atopic comorbidities.
- LEB treatment resulted in robust skin clearance, clinically meaningful QoL impacts, and mental health improvements in adolescent patients with moderate-to-severe AD, regardless of coexisting atopic comorbidities.

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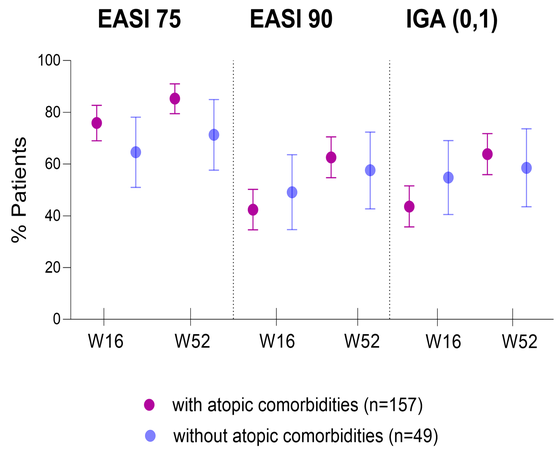
Skin responses were not impacted by atopic comorbidity status

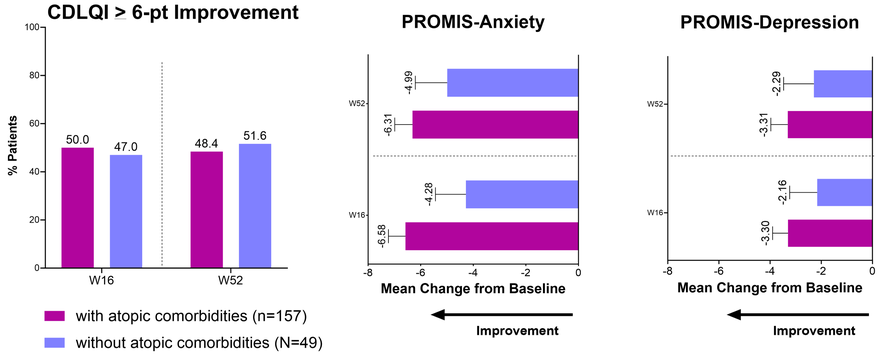


16 Weeks
EASI-75: >60% of patients

1 year
EASI-90 or IGA 0,1: >50%

EASI = Eczema Area and Severity Index; EASI 75 (or EASI 90) = greater than or equal to 75% (or 90%) Improvement in EASI score from baseline; IGA = Investigator's Global Assessment; the upper and lower 95% confidence intervals are shown as error bars.

QoL and mental health improvements were similar in patients with and without atopic comorbidities



AD = atopic dermatitis; QoL = quality of life; CDLQI = Children's Dermatology Life Quality Index; PROMIS = Patient-Reported Outcomes Measurement Information System; PROMIS-A = PROMIS Anxiety; PROMIS-D = PROMIS Depression. For CDLQI data, with atopic comorbidities n=126, without atopic comorbidities n=42.

METHODS

- ADore (NCT04250350) was a Phase 3, open-label 52-week study of lebrikizumab in adolescent patients with moderate-to-severe AD.
- Patients (N=206) were administered a loading dose of 500 mg LEB at baseline and Week (W) 2, followed by 250 mg LEB at W4 and every 2 weeks through W52[a]. Topical therapy was permitted.
- Analysis population: Safety population stratified by patients with or without atopic comorbidities[b].
- Analysis method:
  - For skin and CDLQI endpoints: A combination of non-responder imputation and multiple imputation (NRI/MI) - Data after using systemic rescue medication[c] or discontinuation of treatment due to lack of efficacy were imputed as non-response. Remaining missing data were imputed with multiple imputation.
  - For PROMIS data, Last Observation Carried Forward was used for Change from Baseline.

[a]Patients were not switched to 4-week dosing per the label, as the primary objective of ADore was to assess safety in adolescents. [b]pre-specified medical history assessed at baseline that was considered an "atopic comorbidity". [c]The use of any potency TCS, TCIs and PDE4 inhibitors were permitted as add-on rescue treatment when a participant experienced clinical worsening of symptoms that were intolerable.

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References

1. Paller, Amy S., et al. "Safety and efficacy of lebrikizumab in adolescent patients with moderate-to-severe atopic dermatitis: a 52-week, open-label, phase 3 study." *Dermatology and Therapy* 13.7 (2023): 1517-1534.

At baseline, patients with atopic comorbidities tended to be more severe and/or have a longer duration/earlier age at onset

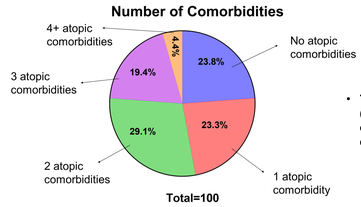
	With Atopic Comorbidities (N = 157)	Without Atopic Comorbidities (N = 49)
Age, years	14.6 (1.82)	14.5 (1.71)
Female, n (%)	82 (52.2)	26 (53.1)
Race, n (%)		
White	108 (68.8)	30 (61.2)
Black or African American	23 (14.6)	3 (6.1)
Asian	14 (8.9)	10 (20.4)
Other[a]	12 (7.6)	6 (12.2)
Ethnicity[b], n (%)		
Hispanic	24 (31.6)	17 (48.6)
Region, n (%)		
United States	76 (48.4)	35 (71.4)
Europe	55 (35.0)	8 (16.3)
Rest of world	26 (16.6)	6 (12.2)
BMI, kg/m^2	25 (6.61)	23.3 (5.13)
Prior systemic treatment, n (%)	**76 (48.4)**	**14 (28.6)**
Age at AD onset, years	**1.8 (3.20)**	**4.0 (5.0)**
Duration since AD onset, years	**12.9 (3.39)**	**10.5 (4.76)**

	With Atopic Comorbidities (N = 157)	Without Atopic Comorbidities (N = 49)
IGA, n (%)		
3 (moderate)	96 (61.1)	37 (75.5)
4 (severe)	**61 (38.9)**	**12 (24.5)**
EASI	**29.7 (12.10)**	**24.6 (9.84)**
BSA, % involvement	**48.7 (22.49)**	**34.8 (18.15)**
DLQI[c]	12.1 (5.35)	13.3 (6.62)
CDLQI[d]	10.4 (5.95)	9.2 (4.97)
PROMIS-Anxiety	52.1 (11.23)	49.8 (11.0)
PROMIS-Depression	49.2 (11.20)	49.5 (12.11)

[a]Other includes American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, Multiple, Other, Not Reported; [b]Ethnicity was assessed for US patients only; [c]Patients >16 years completed the DLQI (n=29 for With Atopic Comorbidities and n=6 for Without Atopic Comorbidities); [d]Patients ≤16 years completed the CDLQI (n=126 for With Atopic Comorbidities and n=42 for Without Atopic Comorbidities).

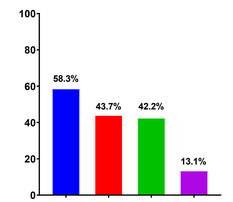
Disclosures:
A. Alexis has received no research grants, has acted as a consultant for Lilly, Sanofi and Regeneron, Amgen, Astra Zeneca, Organon (previously Dermavant), Genentech, and speaker bureau for Sanofi, Regeneron and Incyte. **A. Burnette** has received no research grants, has acted as a consultant for Lilly, Sanofi and Regeneron, Amgen, Astra Zeneca, Organon, Arcutis, and speaker bureau for Lilly, Sanofi and Regeneron, Amgen, Astra Zeneca, Organon. **Z. Chiesa Fuxench** has received research grants from Lilly, LEO Pharma, Regeneron, Sanofi, Trigo, Vanda, Menlo Therapeutics, and Galderma; served as consultant for the Asthma and Allergy Foundation of America, National Eczema Association, AbbVie, Incyte Corporation, and Pfizer; and received honoraria from Regeneron/Sanofi, Pfizer, and Beiersdorf. **C. Flohr** is an investigator in the TREAT and SOFTER trials, the UK-Irish Atopic eczema Systemic Therapy Register and the European Union Horizon 2020-funded BIOMAP Consortium; leads the EU Horizon 2020 Joint Program Initiative-funded Trans-Foods consortium. His department has received funding from Sanofi Genzyme and Pfizer. Speaker/consultancy fees from: Apogee, Almirall, Bioderma, Incyte, LEO, Pfizer, Sanofi. **A. Torrelo** has received fees from Lilly, Sanofi, Viatris, Pfizer for lecturing and advisory boards. **Z. Dawson**, and **E. Pierce** are employees and shareholders of Eli Lilly and Company. **M. Qiao** is an employee of Tigermed. **M. Boguniewicz** has received research grants from Regeneron and been an investigator for Sanofi and Incyte and advisor for AbbVie, Amgen, Dermavant, Incyte, LEO Pharma, Lilly, Pfizer, Regeneron and Sanofi Genzyme.

Number of Comorbidities



- **76% of patients (157/206) had at least one atopic comorbidity**

Frequency of comorbidity



Patients could have had more than 1 comorbidity

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