

Stable Clear-Almost Clear Response is Sustained up to 3 Years in Patients With Moderate-to-Severe Atopic Dermatitis Treated With Lebrikizumab

Jonathan I. Silverberg,¹ Linda Stein Gold,² Peter Lio,³ James Del Rosso,⁴ Andreas Wollenberg,⁵ Jose Manuel Carrascosa,⁶ Gaia Gallo,⁷ Eric Wolf,⁷ Yuxin Ding,⁷ Chao Yang,⁷ Helena Agell,⁸ Christian Vestergaard⁹

¹George Washington University School of Medicine and Health Sciences, Washington, DC, USA; ²Henry Ford Health System, Detroit, USA; ³Northwestern University Feinberg School of Medicine, Chicago, USA; ⁴JDR Dermatology Research Las Vegas, USA; ⁵Augsburg University Hospital, Augsburg, Germany and Comprehensive Center for Inflammation Medicine, University of Luebeck, Luebeck, Germany; ⁶Hospital Universitari Germans Trias i Pujol, UAB, IGTP, Badalona, Spain; ⁷Eli Lilly and Company, Indianapolis, USA; ⁸Almirall, Barcelona, Spain; ⁹Aarhus University Hospital, Aarhus, Denmark

Sponsored by Eli Lilly and Company

OBJECTIVE

- Lebrikizumab, a monoclonal antibody that binds with high affinity and slow off-rate to interleukin (IL)-13, is indicated for the treatment of adults and adolescents (≥12 years of age who weigh ≥40 kg) with moderate-to-severe atopic dermatitis (AD), whose AD is either inadequately controlled with or not suitable for topical therapies.
- Prior analyses from Phase 3 trials (ADvocate1, NCT04146363; ADvocate2, NCT04178967; ADjoin NCT04392154) in patients showed the achievement and maintenance of deep skin response, defined by total skin clearance, through 3 years of lebrikizumab treatment.^{1,2}
- In this post hoc analysis, we assessed the stability of deep skin clearance response up to 3 years in patients who responded to lebrikizumab and who continued the same treatment (lebrikizumab every 4 weeks [Q4W] or every two weeks [Q2W]).

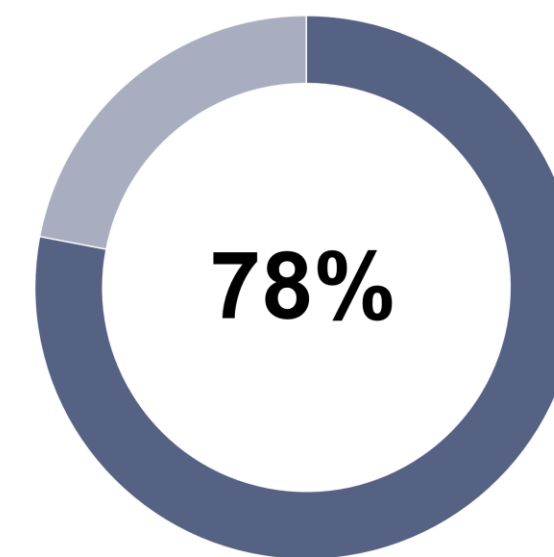
CONCLUSION

- The majority of patients sustained stable clear or almost-clear skin response, as measured by EASI 90 or EASI 100 during 3 years of continuous treatment with lebrikizumab Q4W or Q2W, and approximately 90% did not require TCS.
- This maintenance of response over time provided by lebrikizumab is clinically significant in the context of a chronic and relapsing disease, where long-term disease control remains one of the most critical unmet needs.

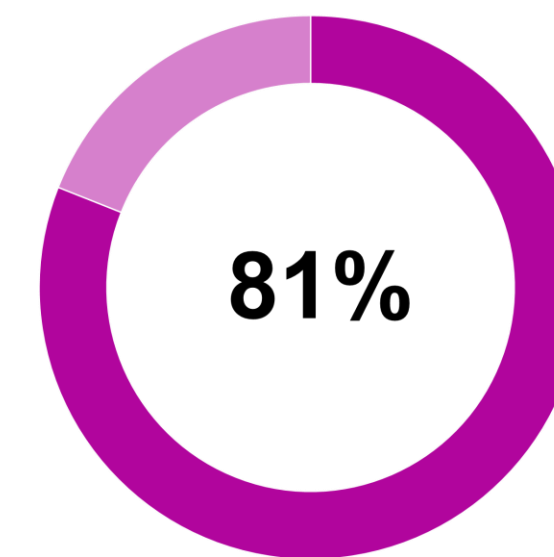
Stable deep response with no or minimal fluctuations through 3 years with lebrikizumab

EASI 90

Proportion of patients with stable EASI 90 response

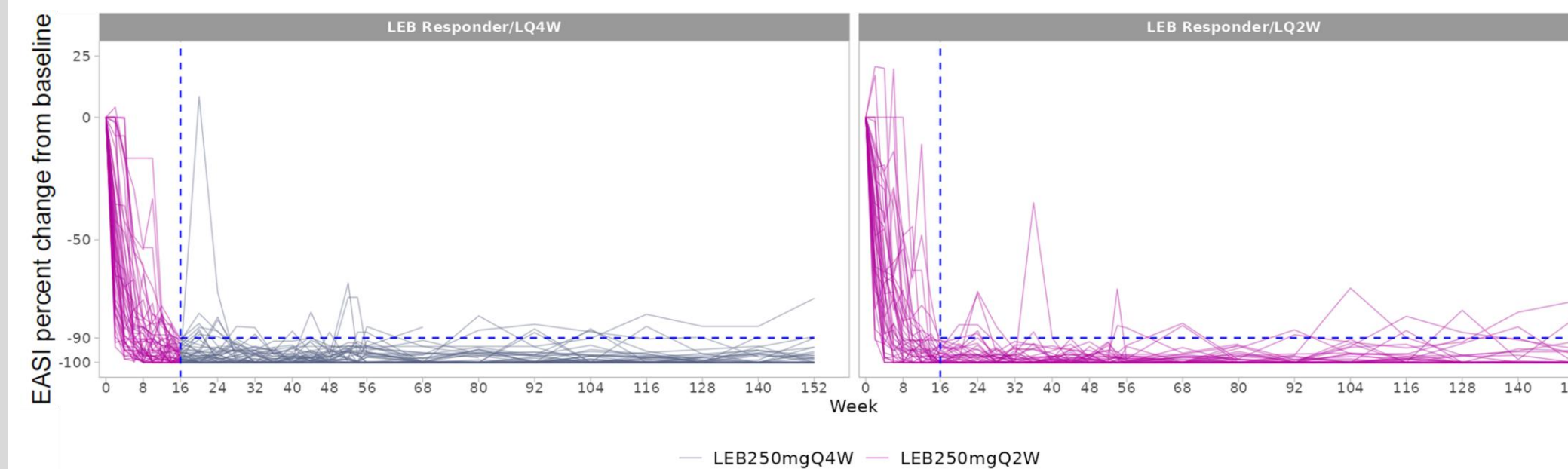


Lebrikizumab Q4W (N=63)



Lebrikizumab Q2W (N=53)

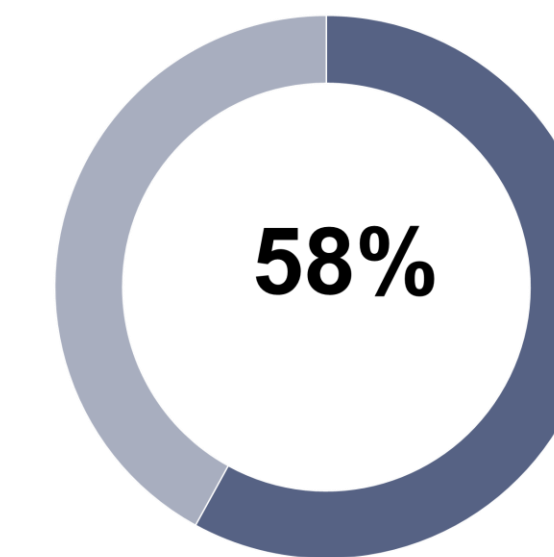
EASI percentage change from baseline for patients who achieved EASI 90 at Week 16 and maintained EASI 90 in ≥80% of visits from Week 16 to 152



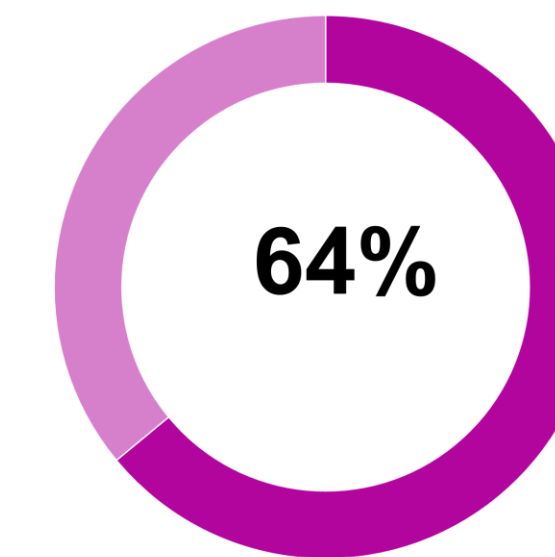
- At Week 16, 64% (63/99) of patients receiving lebrikizumab Q4W and 65% (53/82) of patients receiving lebrikizumab Q2W achieved EASI 90.
- We assessed the proportion of patients who maintained EASI 90 in at least 80% of available visits from Week 16 to 152 among patients who achieved EASI 90 at Week 16.

EASI 100

Proportion of patients with stable EASI 100 response

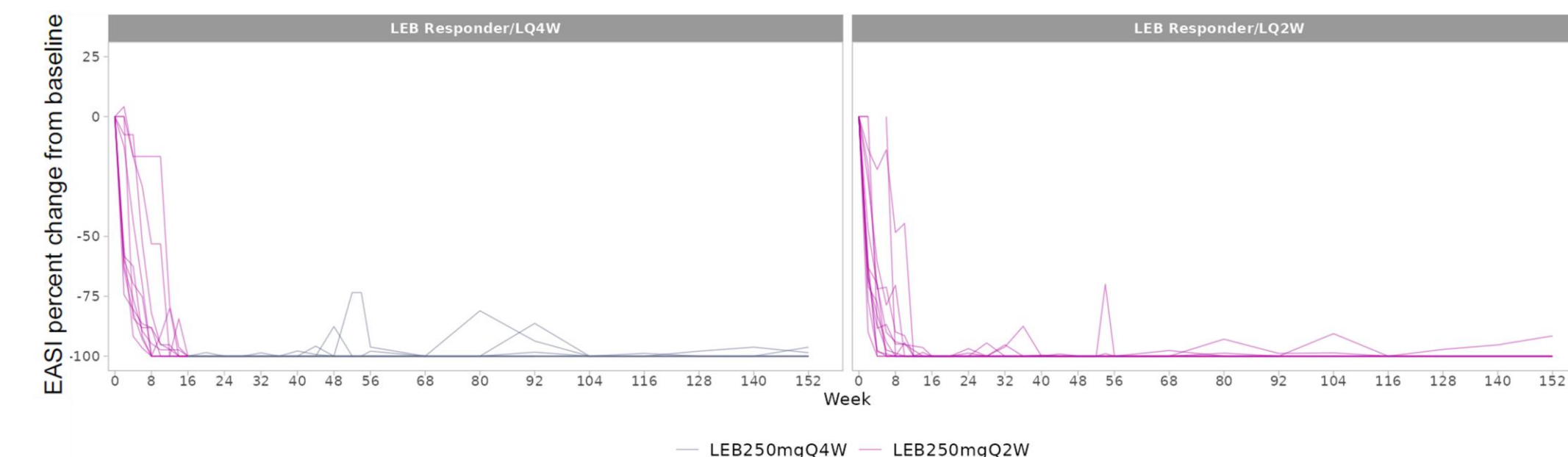


Lebrikizumab Q4W (N=19)



Lebrikizumab Q2W (N=22)

EASI percentage change from baseline for patients who achieved EASI 100 at Week 16 and maintained EASI 100 in ≥80% of visits from Week 16 to 152



- At Week 16, 19% (19/99) of patients receiving lebrikizumab Q4W and 27% (22/82) of patients receiving lebrikizumab Q2W achieved EASI 100.
- We assessed the proportion of patients who maintained EASI 100 in at least 80% of available visits from Week 16 to 152 among patients who achieved EASI 100 at Week 16.

Analysis population, endpoints, and methods

- Analysis population and endpoints
 - Parent studies (study design available via QR code)
 - ADvocate1 and ADvocate2
 - ADjoin
 - Our analysis population consisted of patients who responded to 250-mg lebrikizumab Q2W at Week 16 with ≥90% or 100% reduction in Eczema Area and Severity Index (EASI 90 or EASI 100), completed ADvocate1 and ADvocate2 (1 year), enrolled in the long-term extension study (ADjoin), and received lebrikizumab Q4W or Q2W for an additional 2 years.
 - We assessed the proportion of patients maintaining stable deep skin clearance (EASI 90 or EASI 100) in at least 80% of visits from Week 16 to 152.
- Methods
 - Pruritus daily diary data were collected through Week 104 and not included in this analysis.
 - Descriptive statistics were reported using observed data regardless of rescue medication use.
 - Although TCS use was allowed in ADvocate1 and ADvocate2 maintenance periods and in ADjoin, prior analyses of EASI 75 responders reported that approximately 90% of patients receiving lebrikizumab Q4W or Q2W did not require TCS.¹

Baseline demographics and disease characteristics among Week 16 responders entering ADjoin

	ADvocate1/ADvocate2 → ADjoin*	
	LEBRI 250 mg Q4W (N=99)	LEBRI 250 mg Q2W (N=82)
Mean age, years (SD)	35.8 (17.2)	35.5 (16.2)
Adolescent (≥12 to <18), n (%)	14 (14.1)	11 (13.4)
Female, n (%)	60 (60.6)	42 (51.2)
Region, n (%)		
USA	41 (41.4)	32 (39.0)
Europe	33 (33.3)	32 (39.0)
Rest of the world	25 (25.3)	18 (22.0)
Mean BMI, kg/m ² (SD)	26.4 (6.3)	26.4 (6.2)
Mean duration of disease since AD onset, years (SD)	22.4 (14.2)	23.6 (14.7)
IGA, n (%)		
3 (Moderate)	63 (63.6)	50 (61.0)
4 (Severe)	36 (36.4)	32 (39.0)
Mean EASI score (SD)	28.9 (12.2)	29.2 (11.2)
Mean POEM score (SD)	20.1 (5.8)	21.0 (5.1)
EASI 90 at Week 16, n (%)	63 (63.6)	53 (64.6)
EASI 100 at Week 16, n (%)	19 (19.2)	22 (26.8)

*Data at Week 0 of ADvocate1/ADvocate2 are reported here as baseline data.

References

- Simpson, et al. Poster presentation at: AAD 2025. Presentation number P=63541.
- Silverberg, et al. Poster presentation at: AAD 2024. Presentation number P=52792.

Abbreviations: AAD=American Academy of Dermatology; AD=atopic dermatitis; BMI=body mass index; EASI=Eczema Area and Severity Index; EASI 90/100=at least 90%/100% improvement from baseline in EASI; IGA=Investigator's Global Assessment; L/LEB/LEBRI=lebrikizumab; NRS=numeric rating scale; PNRS=Pruritus Numeric Rating Scale; POEM=Patient-Oriented Eczema Measure; Q2W=every 2 weeks; Q4W=every 4 weeks; SD=standard deviation; TCS=topical corticosteroids

Disclosures: Jonathan I Silverberg has received grants and/or personal fees from AbbVie, Almirall, Amgen, AOBiome, Apollo, Arcutis, Arena, Asana, Aslan, Attovia, BioMx, Biosion, Bodewell, Boehringer-Ingelheim, Bristol-Myers Squibb, Cara, Castle Biosciences, Celgene, Connect Biopharma, Corevitas, Dermavant, Eli Lilly and Company (Lilly), FIDE, Galderma, GlaxoSmithKline, Incyte, Imvengio, Invea, Kiniksa, Leo Pharma, Merck, My-Or Diagnostics, Nektar, Novartis, Optum, Pfizer, RAPT, Recludix, Regeneron, Sandoz, Sanofi-Genzyme, Shaperon, TARGET-RWE, Teva, Union, and UpToDate. Linda Stein Gold has served as an investigator/consultant and/or speaker for Amgen, AbbVie, LEO Pharma, Arcutis, Incyte, Dermavant, Sanofi, Regeneron, Lilly, Bristol Myers Squibb, UCB, Janssen, Ortho Derm, and Galderma. Peter Lio has received grants as an investigator, honoraria for lecturing, and/or consulting fees from AbbVie, AOBiome, Arbonne, Sun's Bae, Dermavant, Dermira, Lilly, Exeltis, Franklin Bioscience/Altus Labs, Incyte, IntraDerm, Johnson & Johnson, Kiniksa, La Roche-Posay/L'Oréal, LEO Pharma, Menlo Therapeutics, The National Eczema Association, Pfizer, Pierre Fabre, Realm Therapeutics, Regeneron/Sanofi Genzyme, Theraplex, TopMD, UCB Pharma, Unilever, and Verrica Pharmaceuticals. James Del Rosso has received grants as an investigator, honoraria for lecturing, and/or consulting fees from AbbVie, Amgen (Celgene), AOBiome, Aslan, Arbonne, Arcutis, Bausch Health (Ortho Derm), Bristol Myers Squibb, Dermavant, Dermira, Lilly, Exeltis, Franklin Bioscience/Altus Labs, Incyte, IntraDerm, Johnson & Johnson, Kiniksa, La Roche-Posay/L'Oréal, LEO Pharma, Menlo Therapeutics, The National Eczema Association, Pfizer, Pierre Fabre, Realm Therapeutics, Regeneron/Sanofi Genzyme, Theraplex, TopMD, UCB Pharma, Unilever, and Verrica Pharmaceuticals. Andreas Wollenberg has served as an advisor and/or paid speaker for and/or participated in clinical trials (with honorarium paid to the institution) sponsored by AbbVie, Allergan, Alentis, Almirall S.A., Amgen, Beiersdorf, Bioderma, Bioproject, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Chugai, DKSH, Lilly, Galapagos, Galderma, Glenmark, GSK, Hans Karrer, Hexal, Janssen-Cilag, Kyowa Kirin, Leo Pharma, L'Oréal, Maruho, MedImmune, MSD, Mylan, MSD, Novartis, Pfizer, Pierre Fabre, Regeneron, Sandoz, Santen, Sanofi-Aventis, and UCB. Jose Manuel Carrascosa has served as an advisor and/or paid speaker for and/or participated in clinical trials sponsored by AbbVie, Almirall S.A., Amgen, Boehringer Ingelheim, Galderma, Janssen-Cilag, LEO Pharma, Lilly, Novartis, Pfizer, Sanofi, Sandoz, and Bristol Myers Squibb. Gaia Gallo, Eric Wolf, Yuxin Ding, and Chao Yang are employees and shareholders of Lilly. Helena Agell is an employee of Almirall S.A. Christian Vestergaard has served as an advisor and/or speaker and/or has received fees or grant and/or research support for and/or has participated in clinical trials sponsored by AbbVie, Almirall, AstraZeneca, Lilly, Galderma, LEO Pharma, Novartis, OM Pharma, Pfizer, Pierre Fabre, and Sanofi Genzyme.

Previously presented at the Maui Derm NP+PA 2025; Colorado Spring, USA; 18-21 June 2025

Acknowledgments: The authors would like to thank all participants, investigators, and trial staff who were involved in the conduct of the trial.

Medical writing assistance was provided by Molly E Tomlin, MS, MD, of Eli Lilly and Company.



Supplemental Materials
Scan the QR code for study design and animations



Scan the QR code for a list of all Lilly content presented at the congress. Other company and product names are trademarks of their respective owners.