

# Achieving Depth of Response in Skin Clearance and Itch Relief With Lebrikizumab is Associated With Minimal Impact of Atopic Dermatitis on Quality of Life

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## OBJECTIVE

- To undertake a post hoc analysis to assess the improvement of quality of life among patients with AD who achieved deep response (total clearance and deep itch relief) with lebrikizumab treatment throughout 1 year in the ADvocate1 and ADvocate2 Phase 3 trials

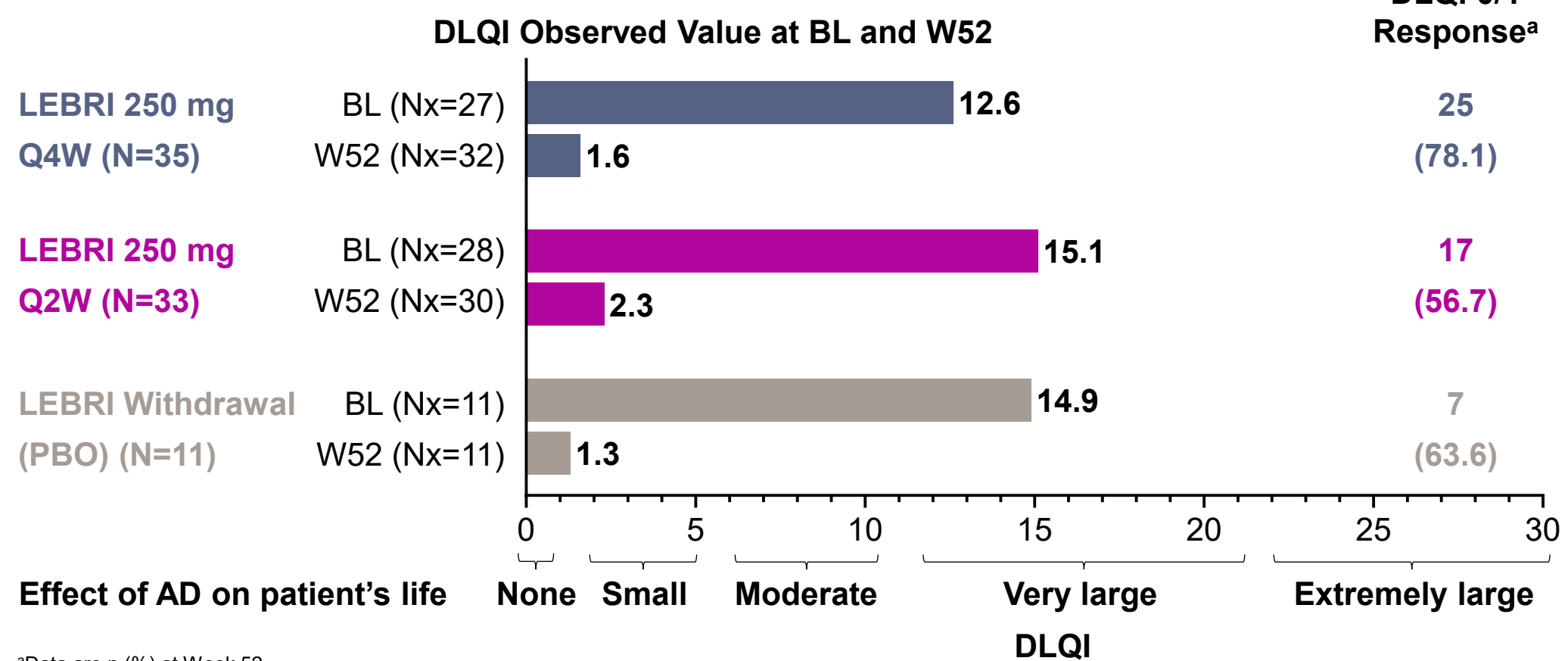
## CONCLUSIONS

- Meaningful DLQI improvements, to levels indicating minimal-to-no impact of AD on quality of life, were experienced by patients under lebrikizumab achieving deep clinical response, as defined by skin clearance and itch relief
- Similar DLQI responses were achieved for deep responders in the lebrikizumab withdrawal arm, suggesting sustained response and consistent impact on quality of life
- This demonstrates that achieving deep response with lebrikizumab is clinically meaningful and has a significant impact on a patient's quality of life

Fall Clinical 2024; Las Vegas, USA; 24-27 October 2024

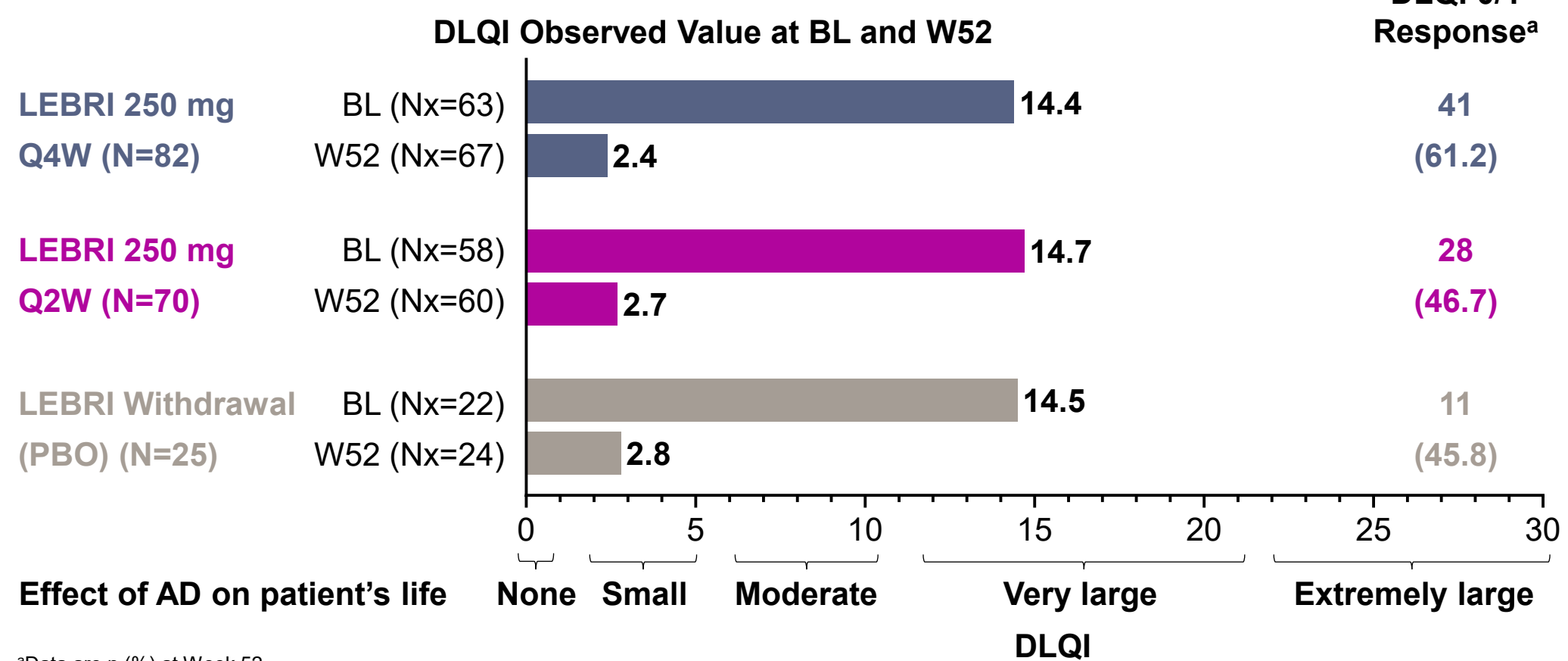
## RESULTS

### IGA 0 Responders at Week 52



<sup>a</sup>Data are n (%) at Week 52. Note: Pooled data results (LEBRI 250 mg Q2W arm + LEBRI 250 mg Q4W arm + PBO arm) were: N=79; BL DLQI=14.0±7.5 (Nx=66), W52 DLQI=1.8±2.7 (Nx=73), and DLQI 0/1 response=49 (67.1) (Nx=73).

### EASI 90 Responders at Week 52



<sup>a</sup>Data are n (%) at Week 52. Note: Pooled data results (LEBRI 250 mg Q2W arm + LEBRI 250 mg Q4W arm + PBO arm) were: N=177; BL DLQI=14.6±7.3 (Nx=143), W52 DLQI=2.6±3.3 (Nx=151), and DLQI 0/1 response=80 (53.0) (Nx=151).

## METHODS

### Key Eligibility Criteria for the ADvocate1 and ADvocate2 Trials

- Adults (≥18 years of age) and adolescents (≥12 to <18 years of age, weighing ≥40 kg)
- Diagnosis of AD, as defined by the American Academy of Dermatology Consensus Criteria, for ≥1 year before screening
- Moderate-to-severe AD, defined as having all the following at the baseline visit:
  - EASI ≥16
  - IGA ≥3
  - BSA involvement ≥10%
- Candidate for systemic therapy

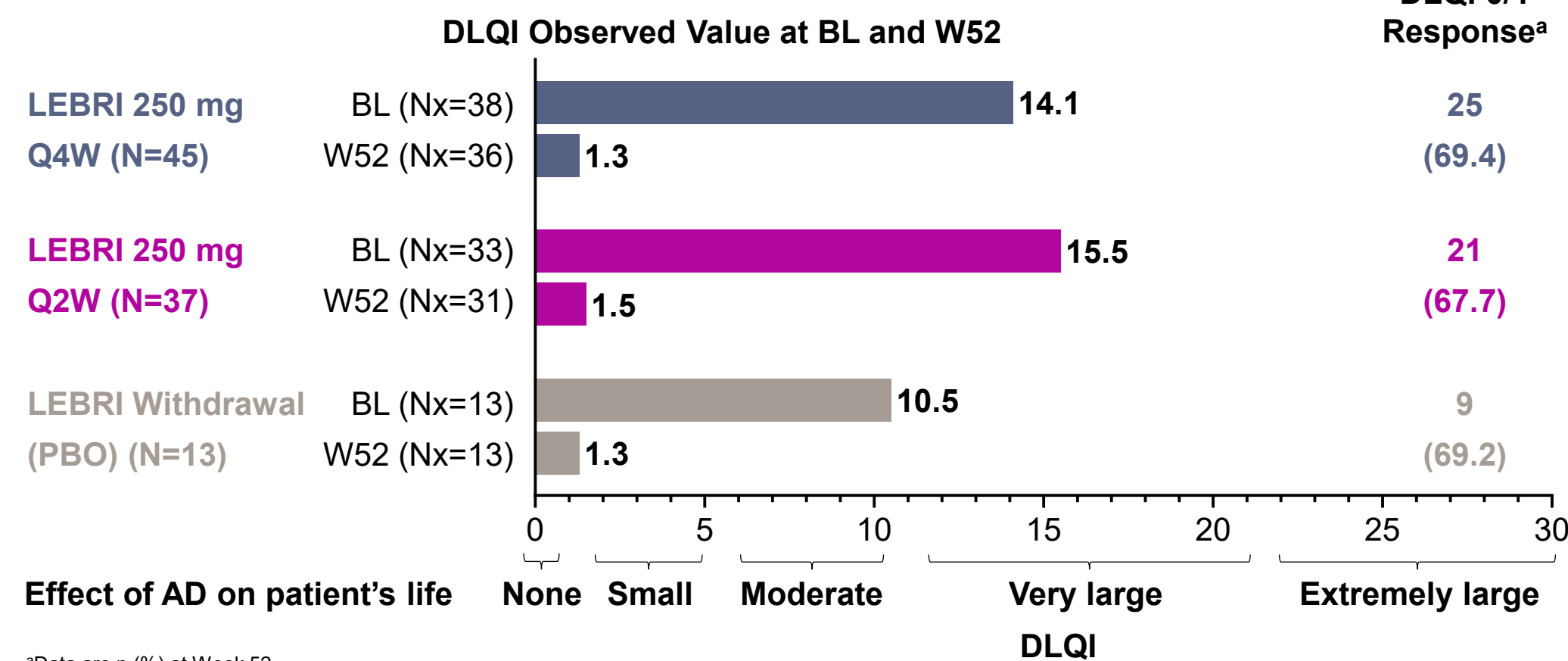
## Outcomes

- Quality of life was assessed by the DLQI<sup>a</sup>
- DLQI total score, change, and percent change from baseline and DLQI (0,1) response rates are reported for Week 16 lebrikizumab responders<sup>b</sup> who achieved the following outcomes at Week 52 (deep responders) separately:
  - IGA 0
  - EASI 90
  - EASI 100
  - Pruritus NRS<sup>c</sup> 0/1

<sup>a</sup>The DLQI is a patient-reported, 10-question, 4-point scale that is used by participants to rate the impact of AD on their quality of life, with higher scores indicating a worse effect of AD on quality of life (maximum score: 30; ≤5: no/minimal effect; ≥11: very large/extremely large effect)<sup>1,2</sup>. <sup>b</sup>Responders were patients who achieved an IGA response of 0 or 1 with a 2-point improvement or EASI 75, without use of rescue medication; <sup>c</sup>Pruritus NRS is a patient-reported, single-item, 11-point scale that is used daily by participants to rate their worst itch severity over the past 24 hours (0 indicating "no itch"; 10 indicating "worst itch imaginable"<sup>3</sup>); <sup>d</sup>The pooled modified MPP excluded 14 patients in the ADvocate2 study (from a single study site), whose eligibility could not be confirmed.

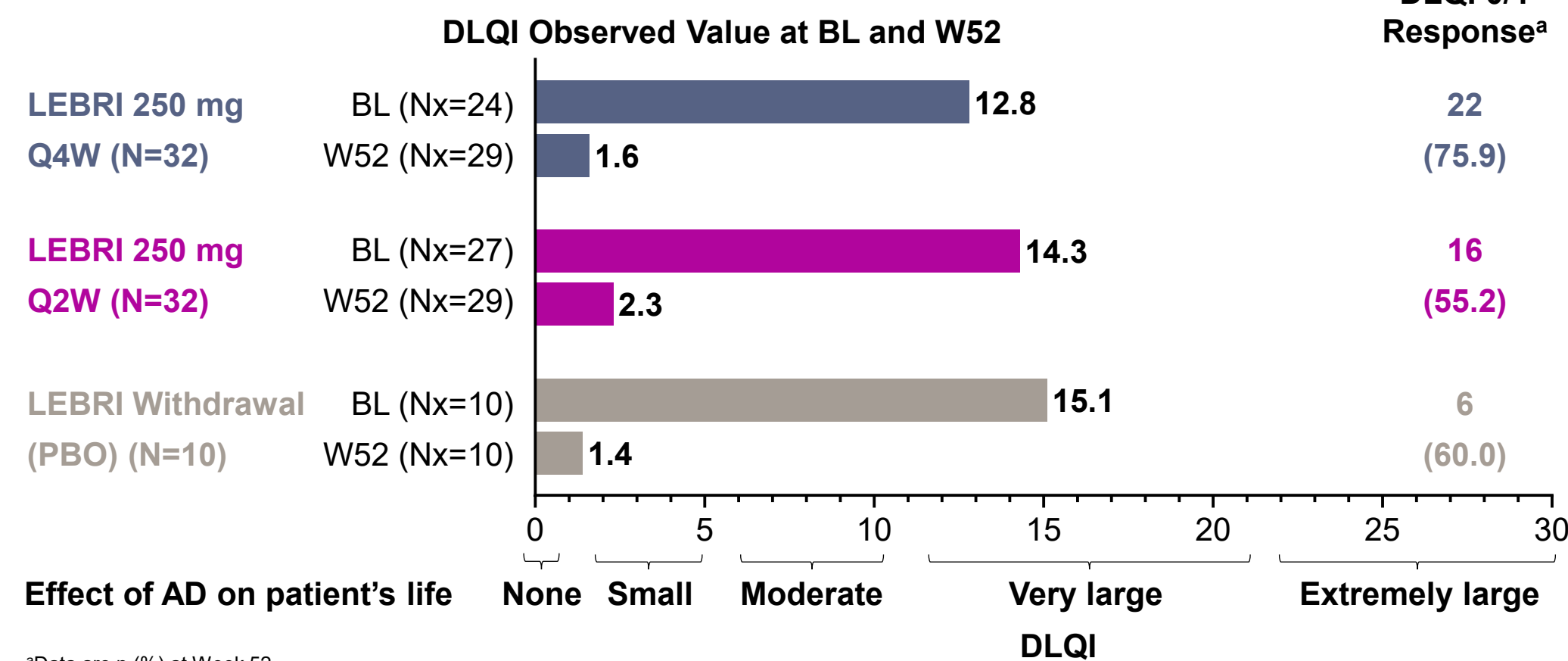
## DLQI Improvement in Deep Responders

### Pruritus NRS 0/1 Responders at Week 52



<sup>a</sup>Data are n (%) at Week 52. Note: Pooled data results (LEBRI 250 mg Q2W arm + LEBRI 250 mg Q4W arm + PBO arm) were: N=95; BL DLQI=14.1±6.8 (Nx=84), W52 DLQI=1.4±1.9 (Nx=80), and DLQI 0/1 response=55 (68.8) (Nx=80).

### EASI 100 Responders at Week 52



<sup>a</sup>Data are n (%) at Week 52. Note: Pooled data results (LEBRI 250 mg Q2W arm + LEBRI 250 mg Q4W arm + PBO arm) were: N=74; BL DLQI=13.9±7.4 (Nx=61), W52 DLQI=1.9±2.8 (Nx=68), and DLQI 0/1 response=44 (64.7) (Nx=68).

## Statistical Analyses

- Analyses were performed in the pooled modified MPP<sup>d</sup> of ADvocate1 and ADvocate2
- "As observed" data were used, regardless of rescue medication use
- Descriptive statistics were reported at baseline and Week 52 by treatment arm for deep responders

**Disclosures:** R. Chovatiya has served as an advisory board member, consultant, and/or investigator for: AbbVie, Apogee Therapeutics, Arcutis, Arena Pharmaceuticals, argenx, ASLAN Pharmaceuticals, Beiersdorf, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Dermavant, Eli Lilly and Company, EPI Health, Incyte Corporation, LEO Pharma, L'Oréal, National Eczema Association, Pfizer, Regeneron, Sanofi, and UCB Pharma; and as a speaker for: AbbVie, Arcutis, Dermavant, Eli Lilly and Company, EPI Health, Incyte Corporation, LEO Pharma, Pfizer, Regeneron, Sanofi, and UCB Pharma; E. Simpson reports personal fees from AbbVie, Advances in Cosmetic Medical Dermatology Hawaii, Amgen, ADBiome, Arcutis, Arena Pharmaceuticals, ASLAN Pharmaceuticals, Bristol Myers Squibb, CorEvitas, Dermira, Eli Lilly and Company, Evelo Biosciences, Excerpta Medica, FIDE, Forte Biosciences, Galderma, GlaxoSmithKline, Impetec Healthcare, Incyte Corporation, Innovaderm Research, Janssen, Johnson & Johnson, Kyowa Kirin, LEO Pharma, Maui Derm, Medscape, Merck, MJH Holding, M.G. Capital, Pfizer, Physicians World, Prime Pharmaceuticals, Redclix Pharma, Regeneron, Revolutionizing Atopic Dermatitis, Rowant Sciences, Sanofi, Trevi Therapeutics, Valeant Pharmaceuticals, Vindico Medical Education, and WebMD; and has received grants or serves as principal investigator for: AbbVie, Acrotech, Amgen, Arcutis, ASLAN Pharmaceuticals, Castle Biosciences, CorEvitas, Dermira, Dermavant, Eli Lilly and Company, Incyte Corporation, Kymab, Kyowa Kirin, National Jewish Health, LEO Pharma, Pfizer, Regeneron, Sanofi, Target RWE, and Versikin. These potential conflicts of interest have been reviewed and managed by Oregon Health & Science University. T. Biedermann gave advice to or received honoraria for talks or research grant from: AbbVie, ALK-Abello, Almirall, Celgene-Bristol Myers Squibb, Eli Lilly and Company, Mylan, Novartis, Phadia-Thermo Fisher, P95 for CureVac, Regeneron, Sanofi, and Viartis; L. Kircik has received grants and/or honoraria from: AbbVie, Acambis, Amgen, Anacor Pharmaceuticals, AnaptysBio, Arcutis, Arena Pharmaceuticals, Assos Pharmaceuticals, Astellas Pharma US, Ausbio Pharma, Dermavant, Dermira, Dow Pharmaceutical Sciences, Eli Lilly and Company, Ferndale Laboratories, Galderma, Genentech, GlaxoSmithKline, Glenmark Pharmaceuticals, HealthPoint, Incyte Corporation, Inocutis Holdings, Inovall Technologies, Kyowa Kirin, LEO Pharma, L'Oréal, nanoBIO, Novartis, NUCCRYST Pharmaceuticals, Onset, Ortho Dermatologies, Ortho Neutrogena, PediaPharma, Pfizer, PharmaDerm, Promius Pharma, PuraCap, Quinova Pharmaceuticals, Regeneron, Sanofi, SkinMedica, Stiefel Laboratories, Sun Pharmaceutical Industries, Taro Pharmaceutical Industries, Triax Pharmaceuticals, and Valeant Pharmaceuticals; V. Shi reports on the board of directors for the Hidradenitis Suppurativa Foundation; is an advisor for: the National Eczema Association; is a shareholder of: LearnHealth; has served as an advisory board member, investigator, speaker, and/or received research funding from: AbbVie, Altus Labs/COUeL, Alumis, Arista Therapeutics, Boehringer Ingelheim, Burt's Bees, Dermira, Eli Lilly and Company, Galderma, Genentech, GSKIN, Incyte Corporation, Kiniksa Pharmaceuticals, LEO Pharma, Menlo Therapeutics, MyOr, Novartis, Pfizer, Polyfins Technology, Regeneron, Sanofi Genzyme, Skin Actives Scientific, Sun Pharma, Target RWE, and UCB Pharma; and has received consultancy payments from: Eli Lilly and Company; I. Figueras-Nart has served as speaker and/or advisor for: AbbVie, Almirall, Celgene, Eli Lilly and Company, LEO Pharma, Novartis, Pfizer, and has received grant support from: LEO Pharma; M. Casillas, G. Gallo, Y. Ding, and E. Pierce are employees and shareholders of: Eli Lilly and Company; H. Zhang is an employee of: TechData Service, which receives funding from: Eli Lilly and Company; H. Agell is an employee of: Almirall; C. Vestergaard has served on advisory boards for: AbbVie, Almirall, Eli Lilly and Company, LEO Pharma, Pfizer, Pierre Fabre, and Sanofi; has been a speaker for: AbbVie, AstraZeneca, Eli Lilly and Company, LEO Pharma, Pfizer, and Sanofi; has been an investigator for: AbbVie, Pfizer, and Sanofi; and received grants from: LEO Pharma and Pfizer. Medical writing assistance was provided by Loredana Spoerri, PhD, of ProScribe – Envision Pharma Group, and was funded by Eli Lilly and Company.

**References**  
 1. Finlay AY, et al. *Clin Exp Dermatol*. 1994;19:210-216. 2. Barbieri JS, et al. *Qual Life Res* 2021;30:1705-1713. 3. Yosipovitch G, et al. *Br J Dermatol*. 2022;186:e145.

**Abbreviations:** AD=atopic dermatitis; BL=baseline; BSA=body surface area; DLQI=Dermatology Life Quality Index; EASI=Eczema Area and Severity Index; EASI 75/90=≥75/90% improvement from baseline in EASI; EASI 100=100% improvement from baseline in EASI; IGA=investigator's Global Assessment; IGA (0,1)=IGA response of clear or almost clear; LEBRI=lebrikizumab; LTE=long-term extension; MPP=maintenance primary population; N=number of patients in the analysis population; NRS=numerical Rating Scale; Nx=number of patients with non-missing values; PBO=placebo; Q2W=every 2 weeks; Q4W=every 4 weeks; SD=standard deviation; W=Week.

This study was funded by Dermira, a wholly owned subsidiary of Eli Lilly and Company, 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.



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