Lebrikizumab Improves Atopic Dermatitis and Quality of Life in Patients With Moderate-to-Severe Atopic Dermatitis Previously Treated With Dupilumab: Results From the ADapt Trial

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OBJECTIVES

- In real-world settings, approximately 18-20% of patients with moderate-to-severe AD discontinue dupilumab within 3-4 years of treatment, and the primary reasons are loss of efficacy (26-40%), AEs (20%), and cost issues and insurance coverage (18%)[1,2]
- The open-label, Phase 3b, 24-week ADapt trial (NCT05369403) aims to assess the efficacy and safety of lebrikizumab in patients previously exposed to dupilumab
  - Other clinical questions include:
    - How are patients with inadequate response to dupilumab likely to respond to lebrikizumab?
    - Are patients who stopped dupilumab because of an AE likely to experience the same AE with lebrikizumab?
- This analysis reports the efficacy and safety of lebrikizumab following 24 weeks of treatment in patients with moderate-to-severe AD previously treated with dupilumab in the ADapt trial

CONCLUSIONS

- Lebrikizumab provides meaningful improvements in skin (including face and hand) clearance, itch, and QoL in patients with moderate-to-severe AD who were previously treated with dupilumab
- The ADapt safety profile is consistent with other lebrikizumab phase 3 trials[3-6]

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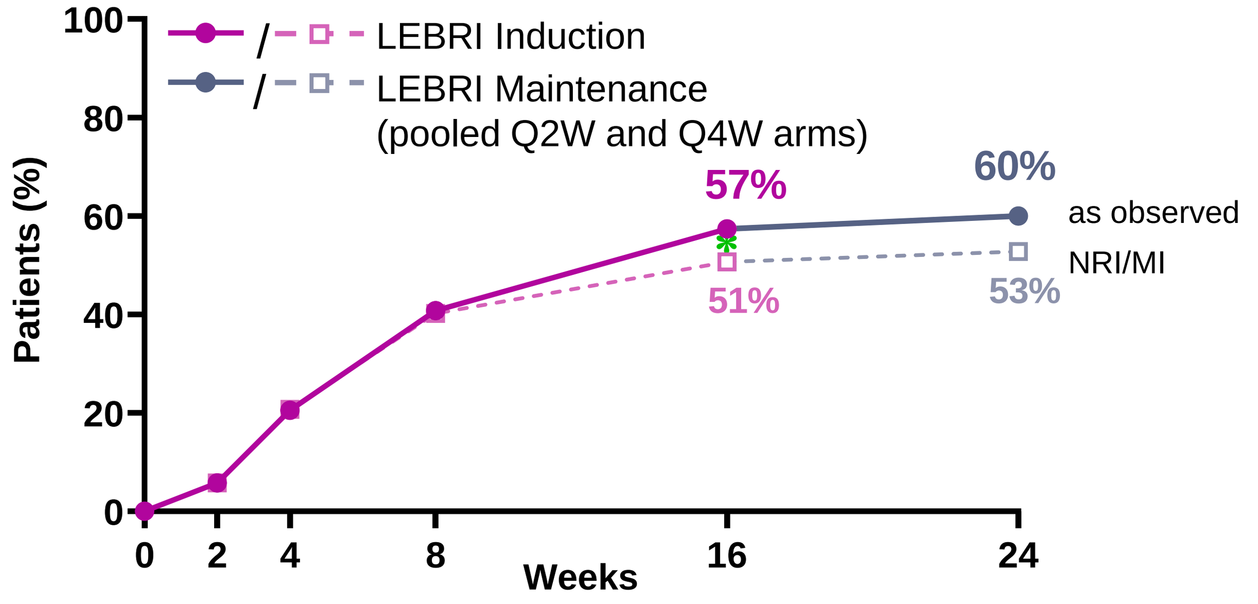
How Efficacious Is Lebrikizumab in Patients Previously Exposed to Dupilumab?

EASI 75

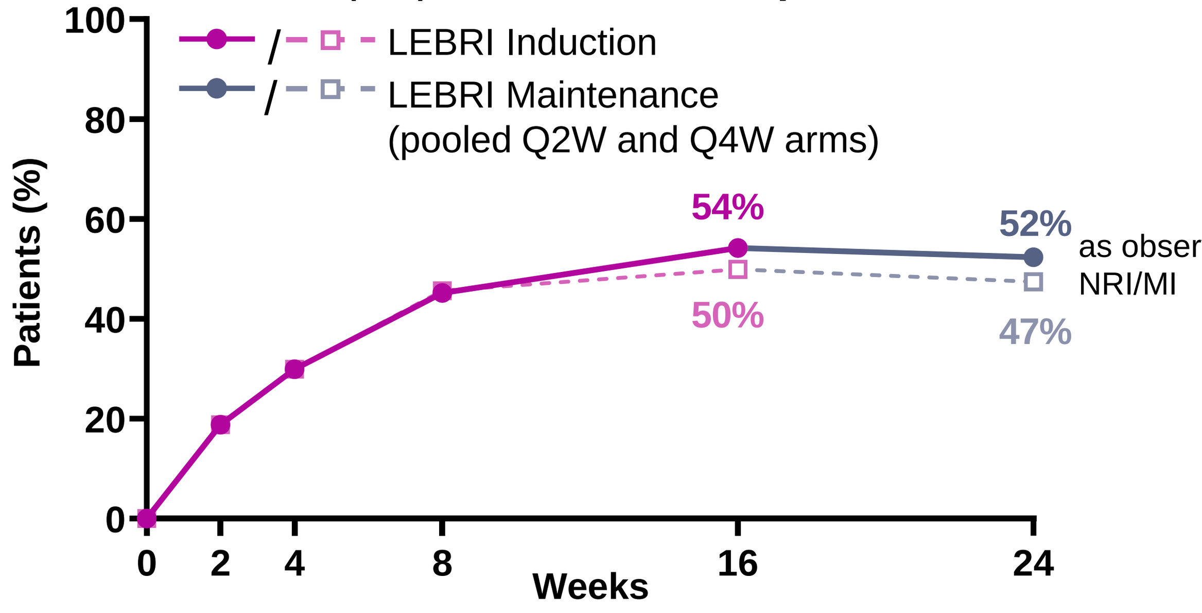


Nx[a]	86	86	83	76	61	55

These results are similar to Phase 3 monotherapy trials of lebrikizumab in patients with moderate-to-severe AD **without** prior dupilumab exposure:

* The EASI 75 response rate at Week 16 using pooled ADvocate 1 & 2 data was 55.4%[4,b]

F-IGA (0,1) With ≥2-Point Improvement[a]



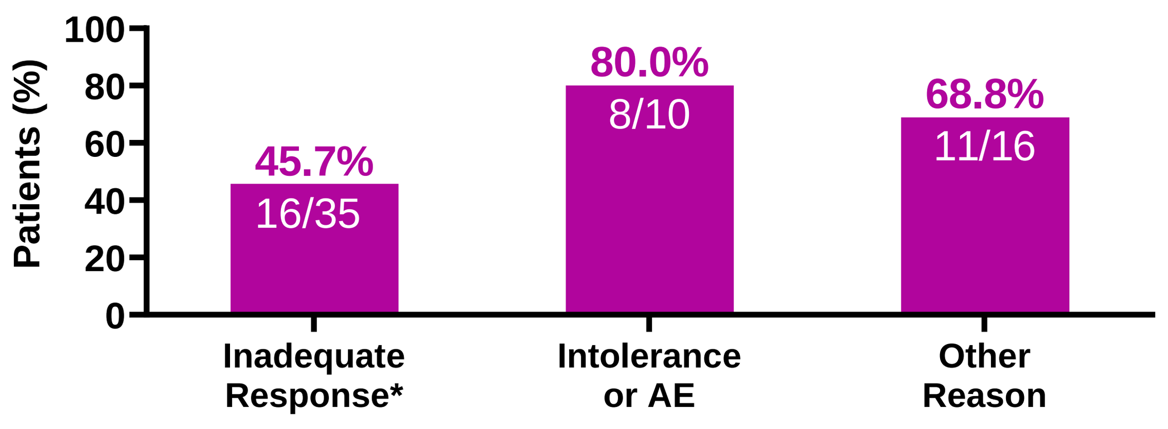
Nx[b]	69	69	67	62	48	44

[a]As observed; [b]In ADvocate 1 and ADvocate2, patients who discontinued treatment due to loss of efficacy or initiated protocol-defined rescue therapy were imputed as non-responders in the NRI/MI analysis.
Notes: NRI/MI analyses are based on all N=86 patients at each timepoint and were performed for Week 0 to Week 24 after pooling together the LEBRI 250 mg Q2W and Q4W arms. Patients who discontinued treatment due to lack of efficacy were imputed as non-responders; all other missing data were imputed using MI.

[a]ITT population with baseline F-IGA ≥2; [b]As observed.
Notes: NRI/MI analyses are based on all N=69 patients at each timepoint and were performed for Week 0 to Week 24 after pooling together the LEBRI 250 mg Q2W and Q4W arms. Patients who discontinued treatment due to lack of efficacy were imputed as non-responders; all other missing data were imputed using MI.

How Are Patients With Inadequate Response to Dupilumab Likely to Respond to Lebrikizumab?

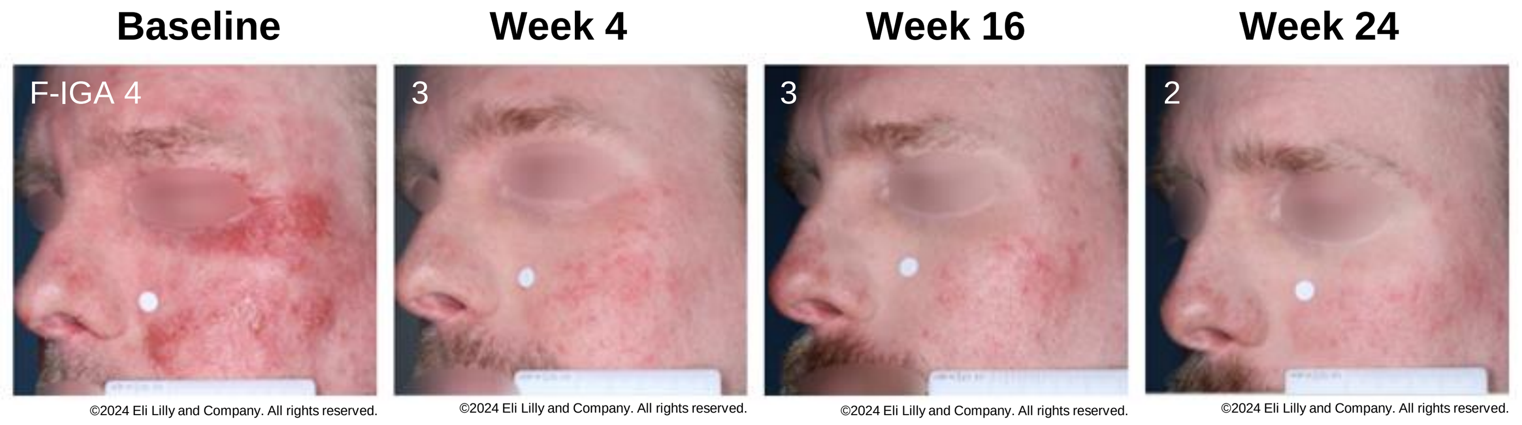
Achievement of EASI 75 at Week 16 by Reason for Prior Dupilumab Discontinuation



*Dupilumab inadequate response subgroup (n/Nx): 2/3 had no response to dupilumab; 7/21 had partial response to dupilumab; and 7/11 lost response to dupilumab

Notes: 61 patients had observed data at Week 0 and Week 16 and were included in this subgroup analysis. Data inside the bars are n/Nx. Reasons for dupilumab discontinuation were patient-reported. The inadequate response group consists of patients who discontinued dupilumab due to no response to treatment, defined as having a peak response for skin and itch that did not improve at all and/or improved less than 25%; partial response to treatment, defined as having a peak response for skin and itch that only improved partially and/or improved between 25% and 50%; or lost response to treatment, defined as having "initially responded but lost response to dupilumab" with respect to skin and/or itch. Other reasons included being unable to afford treatment, health insurance changes, and previous open-label clinical trial participation that completed with no discontinuation for AEs. Due to the small sample size of all subgroups, no conclusions can be drawn from these analyses.

In a Patient Who Discontinued Dupilumab Due to Loss of Response, Lebrikizumab Shows Improvement in Facial Atopic Dermatitis



Lebrikizumab Improved Hand Dermatitis Through Week 24

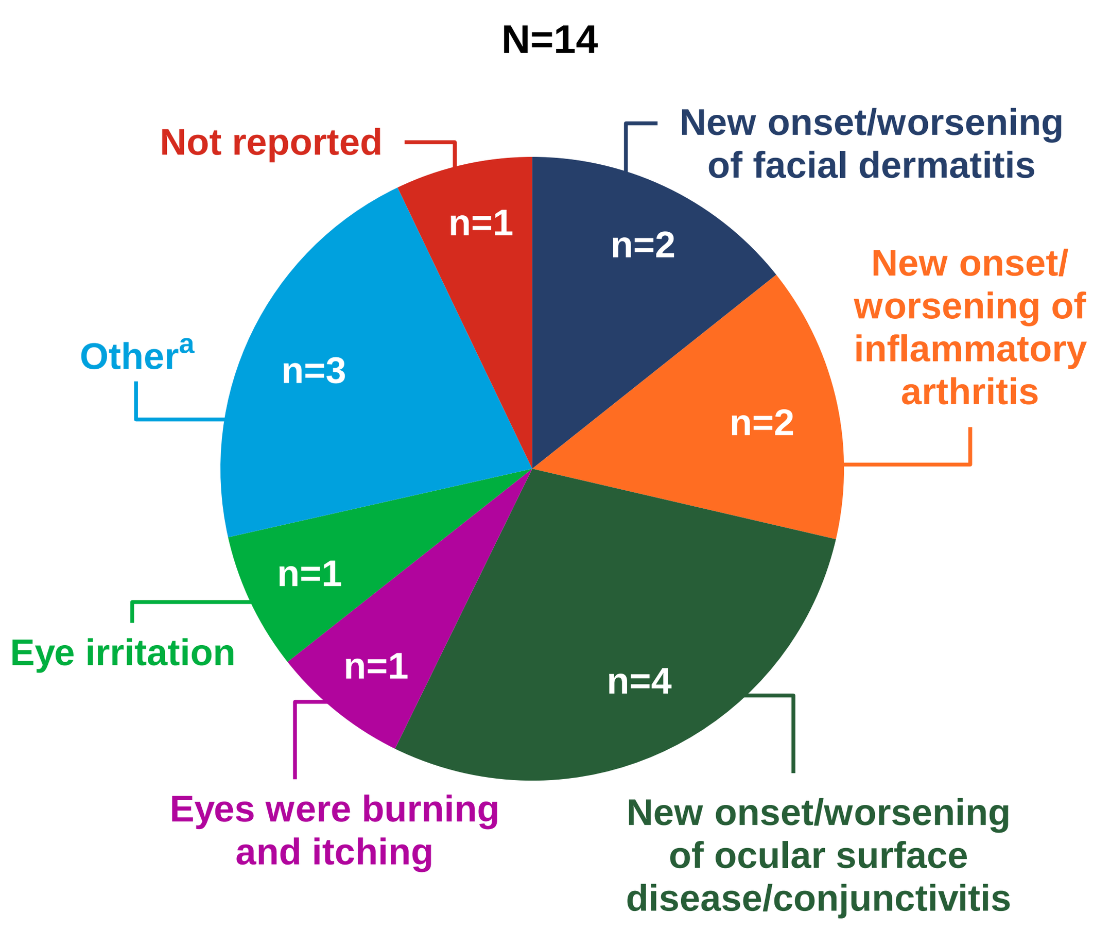
- In dupilumab-experienced patients with moderate-to-severe hand dermatitis at baseline (N=41), defined by mTLSS ≥12, mTLSS decreased by an average of 69% (as observed; NRI/MI, 64%) at Week 16 and by 75% (as observed; NRI/MI, 68%) at Week 24

Notes: NRI/MI analyses are based on all N=41 patients at each timepoint and were performed for Week 0 to Week 24 after pooling together the LEBRI 250 mg Q2W and Q4W arms. Patients who discontinued treatment due to lack of efficacy were imputed as non-responders; all other missing data were imputed using MI.

Are Patients Who Stopped Dupilumab Because of an AE Likely to Experience the Same AE With Lebrikizumab?

Primary Intolerance or AE Leading to Prior Dupilumab Discontinuation

N=14



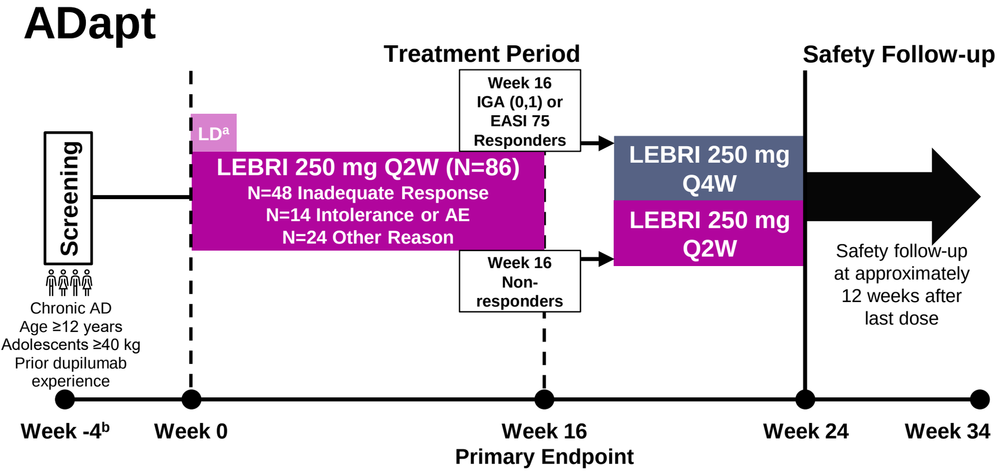
[a]Other includes increased itching; weight gain and worsening of itch; hives, rash, pruritus, and swelling (n=1 each).

In the ADapt Trial

- Of the 10 patients who reported eye-related events, facial dermatitis, or inflammatory arthritis as the reason for prior dupilumab discontinuation, none reported similar events with lebrikizumab
- Of the 14 patients with prior dupilumab discontinuation due to AEs
  - 2 discontinued treatment with lebrikizumab due to an AE:
    - Dermatitis atopic, n=1
    - Immune-mediated rash, n=1

Study Design

ADapt



[a]Patients received LD of 500 mg given SC at Week 0 and Week 2; [b]Screening window was up to 30 days.
Notes: The use of low- and/or mid-potency TCS, TCIs, topical PDE-4 inhibitors, or high-potency TCS up to 10 days was permitted. Patients requiring rescue therapy (high-potency TCS >10 days, topical JAK inhibitors, phototherapy, systemic medication) were discontinued from the study.

Results

Lebrikizumab Improved QoL and Symptoms of Itch Through Week 24

- Of dupilumab-experienced patients with baseline DLQI ≥4 (N=77), 83% (as observed) achieved ≥4-point improvement in DLQI from baseline at Weeks 16 and 24 (NRI/MI, 81% and 80%, respectively)
- Of dupilumab-experienced patients with baseline Pruritus NRS ≥4 (N=62), 53% and 62% (as observed) achieved ≥4-point improvement in Pruritus NRS from baseline at Week 16 and 24 (NRI/MI, 49% and 48%), respectively

Notes: NRI/MI analyses are based on all N=77 or N=62 patients at each timepoint and were performed for Week 0 to Week 24 after pooling together the LEBRI 250 mg Q2W and Q4W arms. Patients who discontinued treatment due to lack of efficacy were imputed as non-responders; all other missing data were imputed using MI.

Baseline Demographics and Disease Characteristics

Characteristic	All LEBRI (N=86)	Reason for Dupilumab Discontinuation[a]: Inadequate Response (N=48)	Intolerance or AE (N=14)	Other Reason (N=24)
Age, years	46.4 (20.0)	43.0 (20.8)	53.1 (15.8)	49.1 (20.0)
Adult (≥18 years), n (%)	77 (89.5)	40 (83.3)	14 (100.0)	23 (95.8)
Adolescent (≥12 to <18 years), n (%)	9 (10.5)	8 (16.7)	0	1 (4.2)
Female, n (%)	41 (47.7)	21 (43.8)	7 (50.0)	13 (54.2)
BMI, kg/m²	27.9 (6.0)	27.2 (5.5)	29.3 (6.7)	28.7 (6.7)
Age at AD onset, years	26.6 (25.9)	22.3 (25.2)	27.4 (25.4)	34.7 (26.6)
Duration since AD onset, years	20.2 (19.9)	21.1 (20.8)	26.2 (21.6)	14.8 (16.2)
IGA, n (%)				
3 (Moderate)	65 (75.6)	33 (68.8)	13 (92.9)	19 (79.2)
4 (Severe)	21 (24.4)	15 (31.3)	1 (7.1)	5 (20.8)
F-IGA, n (%)				
2 (Mild)	21 (24.4)	15 (31.3)	2 (14.3)	4 (16.7)
3 (Moderate)	40 (46.5)	25 (52.1)	6 (42.9)	9 (37.5)
4 (Severe)	8 (9.3)	3 (6.3)	3 (21.4)	2 (8.3)
Pruritus NRS	6.6 (2.4)	6.5 (2.5)	7.0 (2.4)	6.6 (2.2)
≥4, n (%)	62 (87.3)	32 (84.2)	11 (91.7)	19 (90.5)
EASI	24.1 (10.7)	25.8 (12.2)	20.2 (4.3)	22.8 (9.6)
BSA % affected	32.2 (18.5)	35.3 (19.9)	24.8 (11.5)	30.3 (17.7)
DLQI[b]	14.4 (7.0)	15.1 (6.9)	15.4 (7.2)	12.7 (6.8)
mTLSS[c]	10.0 (5.0)	10.4 (5.0)	9.0 (4.4)	9.8 (5.3)
Number of prior systemic treatments,[d] n (%)				
1	50 (58.1)	27 (56.2)	6 (42.9)	17 (70.8)
2	22 (25.6)	13 (27.1)	4 (28.6)	5 (10.8)
≥3	14 (16.3)	8 (16.7)	4 (28.6)	2 (8.3)

[a]Reasons for dupilumab discontinuation were patient-reported. The dupilumab inadequate response subgroup consists of patients who discontinued dupilumab due to no response to treatment, defined as having a peak response for skin and itch that did not improve at all and/or improved less than 25%; partial response to treatment, defined as having a peak response for skin and itch that only improved partially and/or improved between 25% and 50%; or lost response to treatment, defined as "initially responded but lost response to dupilumab" with respect to skin and/or itch. Other reasons included being unable to afford treatment, health insurance changes, previous open-label clinical trial participation that completed with no discontinuation for adverse events; [b]Patients <16 years of age at baseline completed the cDLQI and continued to complete the cDLQI for the duration of the study; [c]41 patients in the all lebrikizumab cohort had mTLSS ≥12, and the mean (SD) score among these patients was 14.0 (2.0); [d]1=dupilumab only, 2=dupilumab and 1 other prior systemic treatment, 3=dupilumab and ≥2 other prior systemic treatments.
Notes: Data are mean (SD) unless stated otherwise. Number of patients with non-missing data was used as the denominator.

AEs[a] Through Week 24

	Pooled LEBRI 250 mg Q2W and Q4W (N=86)
TEAE[b]	46 (53.5)
Mild	26 (30.2)
Moderate	17 (19.8)
Severe	3 (3.5)
SAE	2 (2.3)
Death	0
AE leading to treatment discontinuation[c]	5 (5.8)
TEAE within special safety topics	
Infections	19 (22.1)
Skin infections	1 (1.2)
Potential hypersensitivity[d]	5 (5.8)
Dermatitis atopic	4 (4.7)
Urticaria	1 (1.2)
Injection site reactions[e]	4 (4.7)
Conjunctivitis cluster[f]	3 (3.5)
Malignancies	1 (1.2)
NMSC	1 (1.2)
Malignancies excluding NMSC	0
AD exacerbation	7 (8.1)
Hepatic events	1 (1.2)
Alanine aminotransferase increased	1 (1.2)
Aspartate aminotransferase increased	1 (1.2)

- 3 participants reported TEAEs of conjunctivitis, which were mild or moderate and did not lead to discontinuation

[a]Assessed in patients who received ≥1 dose of LEBRI; [b]Patients with multiple events with different severity were counted under the highest severity; [c]Determined to be due to dermatitis atopic, drug eruption, immune-mediated dermatitis, rash morbilliform, and headache (n=1 each); [d]Events that occurred on the day of drug administration identified using a narrow algorithm search; [e]Injection site reactions are defined using MedDRA high-level term of injection site reactions excluding joint-related Preferred Terms; [f]Defined using the following MedDRA Preferred Terms: conjunctivitis, conjunctivitis allergic, conjunctivitis bacterial, conjunctivitis viral, and giant papillary conjunctivitis.
Note: Data are n (%).

References: 1. Kimball AB, et al. *Dermatol Ther (Heidelb)*. 2023;13:2107-2120. 2. Kang DH, et al. *J Dermatol*. 2024;51:e63-e65. 3. Silverberg JI, et al. *N Engl J Med*. 2023;388:1080-1091. 4. Blauvelt A, et al. *Br J Dermatol*. 2023;188:740-748. 5. Paller AS, et al. *Dermatol Ther (Heidelb)*. 2023;13:1517-1534. 6. Simpson EL, et al. *JAMA Dermatol*. 2023;159:182-191.

Abbreviations: *AD=atopic dermatitis; AE=adverse event; BMI=body mass index; BSA=body surface area; cDLQI=Children's DLQI; DLQI=Dermatology Life Quality Index; EASI=Eczema Area and Severity Index; EASI 75=≥75% improvement from baseline in EASI; F-IGA=Face-IGA; IGA=Investigator's Global Assessment; IGA (0,1)=IGA response of clear or almost clear; ITT=intent-to-treat; JAK=Janus kinase; LD=loading dose; LEBRI=lebrikizumab; mTLSS=modified Total Lesion Symptom Score; 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; Q2W=every 2 weeks; Q4W=every 4 weeks; QoL=quality of life; SAE=serious adverse event; SC=subcutaneous; SD=standard deviation; TCI=topical calcineurin inhibitor; TCS=topical corticosteroids; TEAE=treatment-emergent adverse event; W=Week*

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