Impact of Simultaneous Itch Relief and Substantial Skin Clearance With Lebrikizumab in Patients With Atopic Dermatitis: Post-hoc Analysis From ADvocate1/2

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OBJECTIVE

- To evaluate the impact of simultaneous itch relief and skin clearance on health-related quality of life (HRQoL) and disease burden in patients with moderate-to-severe atopic dermatitis (AD) who were treated with lebrikizumab.

CONCLUSIONS

- In patients with moderate-to-severe AD who were treated with lebrikizumab, those who achieved both itch relief and skin clearance were more likely attain improved outcomes in HRQoL, sleep, skin condition, and itch than those who achieved only one response.
- These findings highlight the importance of achieving simultaneous improvements in both skin lesion severity and itch in managing AD.

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Figure 1: Proportions of patients achieving clinically meaningful outcomes in HRQoL at week 16

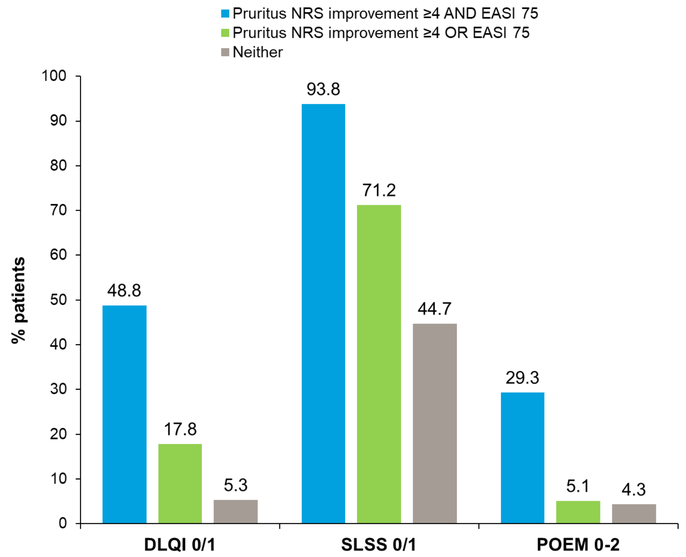
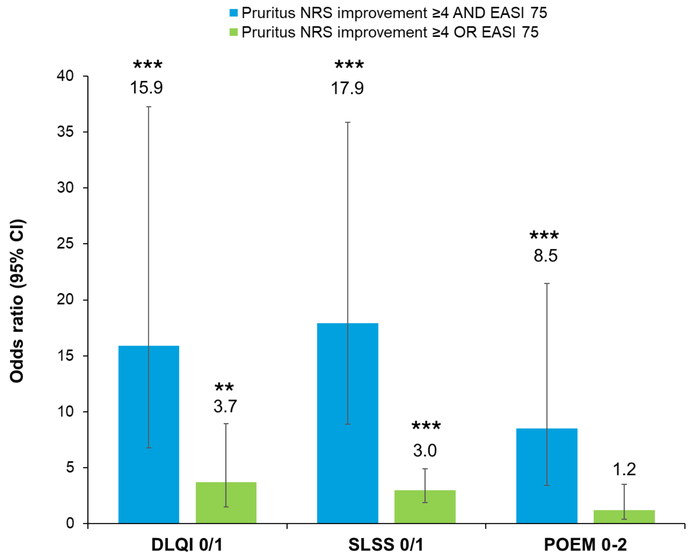


Figure 2: Odds ratios for attaining clinically meaningful outcomes in HRQoL at week 16



- Clinically meaningful outcomes in HRQoL were most frequently attained at week 16 in patients who achieved both itch relief and skin clearance, followed by those who achieved only one response and those who achieved neither response (**Figure 1**).
  - The same pattern was observed for attaining a Pruritus NRS score of 0 or 1 (51.1% vs 10.0% vs 1.6%) or an EASI score of ≤7 (94.9% vs 68.8% vs 12.2%) at week 16.
- Patients who achieved both responses were more likely to attain DLQI 0/1, SLSS 0/1, and POEM 0-2 than those who achieved only one response (**Figure 2**).

**p<0.01, ***p<0.001 versus patients who achieved neither response. Patient groups were mutually exclusive.

CI, confidence interval; DLQI 0/1, Dermatology Life Quality Index of 0 or 1; EASI 75, ≥75% improvement from baseline in the Eczema Area and Severity Index; POEM 0-2, Patient-Oriented Eczema Measure score of 0 to 2; Pruritus NRS improvement ≥4, ≥4-point improvement from baseline in the Pruritus Numerical Rating Scale score; SLSS 0/1, Sleep-Loss Numerical Rating Scale score of 0 or 1.

SYNOPSIS

- AD imposes substantial disease burden on patients and impairs HRQoL due to chronic itching and skin inflammation.[1]
- Lebrikizumab is a monoclonal antibody that inhibits interleukin-13 signaling[2] and has been approved for the treatment of moderate-to-severe AD.[3]
- In the phase 3 ADvocate1 (NCT04146363) and ADvocate2 (NCT04178967) trials,[4] patients more frequently achieved ≥75% improvement from baseline in the Eczema Area and Severity Index (EASI 75) plus ≥4-point improvement from baseline in the Pruritus Numerical Rating Scale score (Pruritus NRS improvement ≥4) with lebrikizumab than with placebo (31.9% vs 5.2%) at week 16.[5]
- Real-world data suggest that achieving optimal treatment targets for skin clearance and itch is associated with better HRQoL and patient-reported outcomes in patients with AD.[6,7]
- This post hoc analysis evaluated the impact of achieving simultaneous itch relief and skin clearance at week 16 on HRQoL and disease burden in patients treated with lebrikizumab, using pooled data from ADvocate1 and ADvocate2.
- The results showed that achieving both itch relief and skin clearance was associated with greater odds of attaining a clinically meaningful outcome compared to partial improvements in itch or skin alone.

References

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METHODS

- In ADvocate1 and ADvocate2, adults (≥18 years old) and adolescents (12 to <18 years old, weight ≥40 kg) with moderate-to-severe AD (EASI ≥16; Investigator's Global Assessment ≥3, and body surface area involvement ≥10%) were randomized 2:1 to receive subcutaneous lebrikizumab 250 mg or placebo every 2 weeks during the induction period (through week 16).
- Data were pooled from the induction period of these trials.
- The analysis included patients from the lebrikizumab arm who had baseline and week-16 assessments for the Pruritus NRS and EASI and a baseline Pruritus NRS score of ≥4.
- A logistic regression model was used to estimate the odds ratio of experiencing clinically meaningful outcomes at week 16 for patients who achieved both EASI 75 and Pruritus NRS improvement ≥4 and patients who achieved either response, each compared with those who achieved neither response.
- The Firth logistic regression option was used to reduce the bias related to the small sample size and to account for sparse data in outcome categories.
- Observed data were used without imputation for missing values.

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RESULTS

Table 1: Baseline demographic and disease characteristics

	Response achieved at week 16		
	Pruritus NRS improvement ≥4 AND EASI 75 (n=178)	Pruritus NRS improvement ≥4 OR EASI 75 (n=170)	Neither (n=123)
Age, mean (SD), y	37.3 (17.1)	34.8 (16.7)	36.9 (17.3)
Adolescents (12 to <18 y), n (%)	19 (10.7)	21 (12.4)	11 (8.9)
Adults (>18 y), n (%)	159 (89.3)	149 (87.6)	112 (91.1)
Female, n (%)	91 (51.1)	87 (51.2)	47 (38.2)
BMI, mean (SD), kg/m^2	25.8 (5.7)	26.0 (5.6)	27.2 (5.9)
Age at AD onset, mean (SD), y	15.9 (20.1)	13.8 (19.2)	14.6 (19.4)
Time since AD onset, mean (SD), y	21.8 (15.1)	21.4 (14.4)	22.6 (15.7)
Prior systemic treatment, n (%)	94 (52.8)	87 (51.2)	78 (63.4)
IGA, n (%)			
3 (Moderate)	98 (55.1)	105 (61.8)	69 (56.1)
4 (Severe)	80 (44.9)	65 (38.2)	54 (43.9)
EASI score, Mean (SD)	30.5 (12.1)	28.9 (11.6)	30.1 (10.9)
BSA % affected, Mean (SD)	47.0 (22.7)	45.7 (21.8)	47.6 (24.6)
Pruritus NRS score, Mean (SD)	7.8 (1.4)	7.2 (1.7)	7.4 (1.6)
DLQI score, Mean (SD)	16.5 (7.1); n=148	14.8 (7.1); n=136	16.7 (6.9); n=99
SLSS, Mean (SD)	2.4 (0.9); n=176	2.3 (0.9); n=170	2.4 (0.9); n=123
POEM score, Mean (SD)	21.4 (5.2); n=173	21.0 (5.3); n=166	21.9 (4.8); n=121

Patient groups were mutually exclusive. AD, atopic dermatitis; BMI, body mass index; BSA, body surface area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; POEM, Patient-Oriented Eczema Measure; Pruritus NRS, Pruritus Numerical Rating Scale; Pruritus NRS improvement ≥4, ≥4-point improvement from baseline in the Pruritus NRS; SD, standard deviation; SLSS, Sleep-Loss Numerical Rating Scale.

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