P-63541

Raising the Bar of Efficacy in Atopic Dermatitis: Lebrikizumab Maintains Depth of Response Over 3 Years in Week 16 Responders

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OBJECTIVE

- To report maintenance of deep response and quality of life with 3 years of continuous treatment of lebrikizumab in responders[a] from ADvocate1&2 (NCT04146363; NCT04178967)[1] enrolled into the extension study ADjoin (NCT04392154)[2]

[a]Responders in ADvocate1&2 were defined as those patients who achieved either EASI 75 or IGA (0,1) following 16 weeks of LEBRI 250 mg Q2W treatment without use of rescue therapy.

CONCLUSIONS

- Under lebrikizumab maintenance treatment in Week 16 responders, approximately 8 out of 10 achieved almost clear skin (as indicated by EASI 90) up to 3 years; additionally, over 50% of patients experienced total skin clearance, as assessed by EASI 100 or IGA (0)
- Quality of life was maintained through 3 years of continuous lebrikizumab treatment in Week 16 responders; approximately 1 out of 3 patients reported minimal to no AD-specific symptoms, as assessed by POEM (0,1), at Week 152
- Most patients did not require use of rescue therapy (TCS, TCI, or systemic treatment) with continuous lebrikizumab treatment
- These 3-year data suggest that long-term maintenance of total skin clearance is an achievable treatment goal for at least half of lebrikizumab Week 16 monotherapy responders

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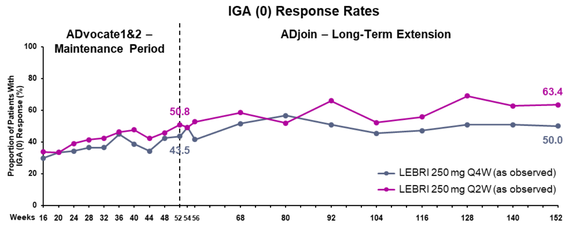
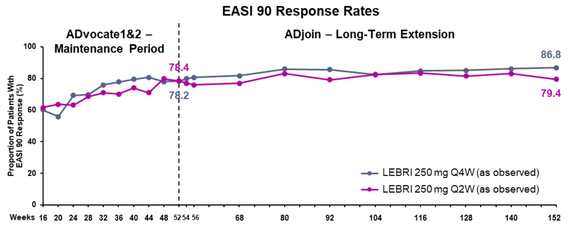
KEY RESULTS

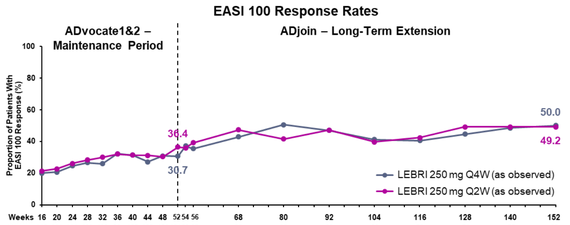
Deep Responses Were Maintained and Improved in Lebrikizumab Week 16 Responders Up to Week 152 for Both Q4W and Q2W Dosing



Notes: Data from Week 16 responders achieving IGA (0,1) at Week 16 of parent study. Not all patients completing ADvocate1 and ADvocate2 were enrolled to ADjoin; Week 52 data are from ADvocate1&2 parent studies.



Notes: Data from Week 16 responders achieving EASI 75 at Week 16 of parent study. Not all patients completing ADvocate1 and ADvocate2 were enrolled to ADjoin; Week 52 data are from ADvocate1&2 parent studies.



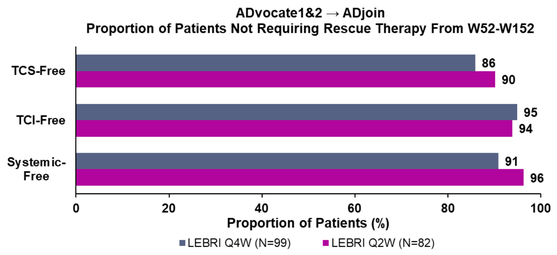
Notes: Data from Week 16 responders achieving EASI 75 at Week 16 of parent study. Not all patients completing ADvocate1 and ADvocate2 were enrolled to ADjoin; Week 52 data are from ADvocate1&2 parent studies.

Baseline Demographics and Disease Characteristics

	ADvocate1&2 → ADjoin[a]	
	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/m² (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)

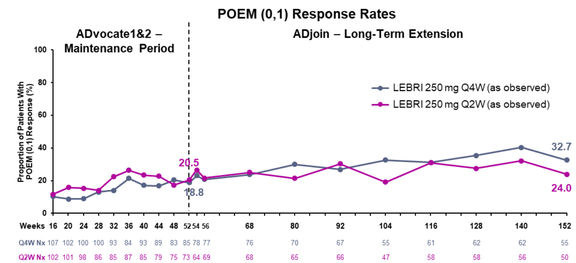
[a]Data at Week 0 of ADvocate1&2 are reported here as baseline data.

Most Patients Receiving Lebrikizumab Q4W and Q2W Through 152 Weeks Did Not Require Rescue Therapy[a]



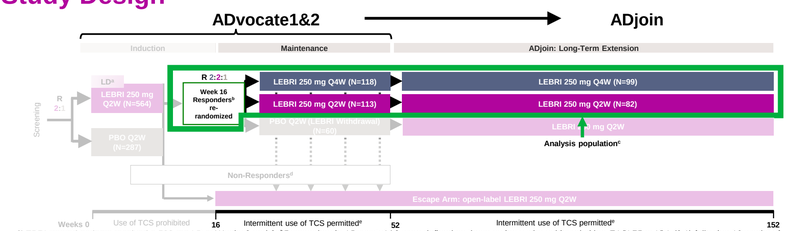
[a]Rescue therapy included any topical or systemic therapy during the treatment period.
Notes: Topical rescue therapy included TCS and TCIs. Systemic rescue therapy included systemic corticosteroids, immunosuppressants, biologics, phototherapy, and photochemotherapy. The majority of systemic rescue was used to treat TEAEs. Patients may have received more than 1 form of rescue therapy.

POEM (0,1) Response Was Maintained and Improved Through 152 Weeks for Both Q4W and Q2W Dosing



Note: Data from Week 16 responders of parent study. Not all patients completing ADvocate1 and ADvocate2 were enrolled to ADjoin; Week 52 data are from ADvocate1&2 parent studies.

Study Design



[a]LEBRI-treated patients received a 500-mg LD at Weeks 0 and 2; [b]Responders in ADvocate1&2 were defined as those patients who achieved either EASI 75 or IGA (0,1) following 16 weeks of LEBRI 250 mg Q2W treatment without use of rescue therapy; [c]LEBRI responders randomized to LEBRI 250 mg Q2W or LEBRI 250 mg Q4W at Week 16 (ADvocate1&2), and enrolled into ADjoin at Week 52 with the same dosage regimen; [d]Patients who required short-term systemic treatment for AD in the Maintenance and Long-Term Extension Periods were assessed on a case-by-case basis.
Note: This analysis did not include per-protocol non-responders, defined as patients who used rescue therapy (including topical) during the 16-week Induction Period and assigned to receive open-label LEBRI 250 mg Q2W as part of the Escape Arm; additionally, during the 36-week Maintenance Period, patients who did not maintain EASI 50 (assessed at Weeks 24, 32, 40, 48) were also assigned to the Escape Arm. Once in the Escape Arm, patients who did not achieve EASI 50 after at least 8 weeks of treatment were terminated from the study. Non-responders receiving systemic rescue medication were required to washout for 5 half-lives prior to initiating treatment in the Escape Arm. In the Long-Term Extension Period, patients who did not achieving an EASI-50, from parent study baseline, by Week 16, maintaining an EASI-50 response, or not achieving clinical benefit were terminated from study. Additionally, in the Escape Arm, intermittent use of TCS for patients who required short-term systemic treatment for AD (assessed on a case-by-case basis) was permitted, but patients requiring long-term systemic treatment (eg, non-responders) were discontinued from the study.

Parent Studies (ADvocate1&2)

- Adults (≥18 years) and adolescents (≥12 to <18 years; weight ≥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%

ADjoin

- Patients could be included if they completed the study treatment and the last patient visit of the parent trial
- Patients were excluded if in the parent trial they:
  - Developed an SAE related to lebrikizumab or an AE related to lebrikizumab that led to treatment discontinuation, which indicated that continued treatment with lebrikizumab could present an unreasonable risk for the patient
  - Met conditions in the previous parent study consistent with protocol-defined criteria for permanent study drug discontinuation, if deemed related to lebrikizumab or if led to investigator- or sponsor-initiated withdrawal of patient from the study (eg, non-compliance, inability to complete study assessments)

Outcomes

- Deep response was assessed using:
  - IGA (0) (in Week 16 responders achieving IGA [0,1] at Week 16 of parent study)
  - EASI 90 (in Week 16 responders achieving EASI 75 at Week 16 of parent study)
  - EASI 100 (in Week 16 responders achieving EASI 75 at Week 16 of parent study)
- Quality of life was assessed using:
  - Total score POEM[3] (0,1) in Week 16 responders
    - POEM is a validated, patient-reported, 7-item questionnaire that assesses AD-specific symptoms over the past week
      - Patients respond to questions about the frequency of itch, sleep disturbance, bleeding, weeping/oozing, cracking, flaking, and dryness/roughness, with each symptom scored from 0 to 4 (*0=no days; 1=1 to 2 days; 2=3 to 4 days; 3=5 to 6 days; and 4=every day*)
      - Total scores range from 0 to 28, with lower total score indicating better quality of life

Note: Responders in ADvocate1&2 were defined as those patients who achieved either EASI 75 or IGA (0,1) following 16 weeks of LEBRI 250 mg Q2W treatment without use of rescue therapy.

Statistical Analyses and Assessment

- Analysis populations:
  - **Parent studies (ADvocate1&2):** Week 16 lebrikizumab responders[a] randomized to lebrikizumab 250 mg Q4W or lebrikizumab 250 mg Q2W
  - **ADjoin:** Lebrikizumab responders[a] randomized to lebrikizumab 250 mg Q4W or lebrikizumab 250 mg Q2W at Week 16 (ADvocate1&2), and enrolled into ADjoin at Week 52 with the same dosage regimen
- Efficacy analyses:
  - Descriptive statistics were reported using all collected as-observed data, regardless of rescue medication use

[a]Responders were defined as those patients who achieved either EASI 75 or IGA (0,1) following 16 weeks of LEBRI 250 mg Q2W treatment without use of rescue therapy in ADvocate1&2.

Abbreviations: *AD=atopic dermatitis; AE=adverse event; BMI=body mass index; BSA=body surface area; EASI=Eczema Area and Severity Index; EASI 75/90/100=≥75%/≥90%/100% improvement from baseline in EASI; IGA=Investigator's Global Assessment; IGA (0)=IGA response of clear; IGA (0,1)=IGA response of clear or almost clear; LD=loading dose; LEBRI=lebrikizumab; N=number of patients with non-missing values; PBO=placebo; POEM=Patient-Oriented Eczema Measure; Q2W=every 2 weeks; Q4W=every 4 weeks; R=randomization; SAE=serious AE; SD=standard deviation; TCI=topical calcineurin inhibitor; TCS=topical corticosteroid; TEAE=treatment-emergent AE*

References

1. Blauvelt A, et al. *Br J Dermatol.* 2023;188:740-748.
2. Thaçi D, et al. Oral presentation at: *EADV 2025*. Presentation number D1T01.2.
3. Charman CR, et al. *Arch Dermatol.* 2004;140:1513-1519.

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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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Objective

- To report maintenance of deep response and quality of life with 3 years of continuous treatment of lebrikizumab in responders[a] from ADvocate1&2 (NCT04146363; NCT04178967)[1] enrolled into the extension study ADjoin (NCT04392154)[2]

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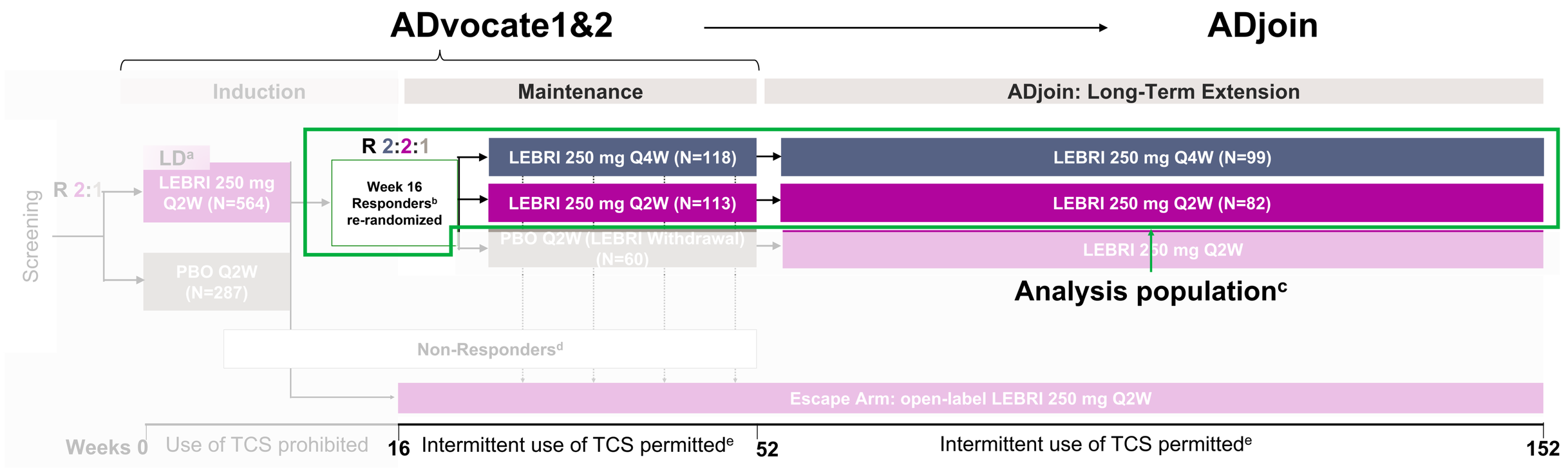
EASI=Eczema Area and Severity Index; EASI 75=≥75% improvement from baseline in EASI; IGA=Investigator's Global Assessment; IGA (0,1)=IGA response of clear or almost clear; LEBRI=lebrikizumab; Q2W=every 2 weeks.

Study Design



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Note: This analysis did not include per-protocol non-responders, defined as patients who used rescue therapy (including topical) during the 16-week Induction Period and assigned to receive open-label LEBRI 250 mg Q2W as part of the Escape Arm; additionally, during the 36-week Maintenance Period, patients who did not maintain EASI 50 (assessed at Weeks 24, 32, 40, 48) were also assigned to the Escape Arm. Once in the Escape Arm, patients who did not achieve EASI 50 after at least 8 weeks of treatment were terminated from the study. Non-responders receiving systemic rescue medication were required to washout for 5 half-lives prior to initiating treatment in the Escape Arm. Patients who were receiving placebo in the Maintenance Phase will receive a loading dose of LEBRI 500 mg at the time of enrollment (baseline) and at Week 2 followed by 250 mg LEBRI Q2W. In the Long-Term Extension Period, patients who did not achieving an EASI-50, from parent study baseline, by Week 16, maintaining an EASI-50 response, or not achieving clinical benefit were terminated from study. Additionally, in the Escape Arm, intermittent use of TCS for patients who required short-term systemic treatment for AD (assessed on a case-by-case basis) was permitted, but patients requiring long-term systemic treatment (eg, non-responders) were discontinued from the study.

AD=atopic dermatitis; EASI=Eczema Area and Severity Index; EASI 75=≥75% improvement from baseline in EASI; IGA=Investigator's Global Assessment; IGA (0,1)=IGA response of clear or almost clear; LD=loading dose; LEBRI=lebrikizumab; PBO=placebo; Q2W=every 2 weeks; Q4W=every 4 weeks; R=randomization; TCS=topical corticosteroid.

Key Eligibility Criteria

Parent Studies (ADvocate1&2)

- Adults (≥18 years) and adolescents (≥12 to <18 years; weight ≥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:
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ADjoin

- Patients could be included if they completed the study treatment and the last patient visit of the parent trial
- Patients were excluded if in the parent trial they:
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AD=atopic dermatitis; AE=adverse event; BSA=body surface area; EASI=Eczema Area and Severity Index; IGA=Investigator's Global Assessment; SAE=serious AE.

Outcomes

- Deep response was assessed using:
  - IGA (0) (in Week 16 responders achieving IGA [0,1] at Week 16 of parent study)
  - EASI 90 (in Week 16 responders achieving EASI 75 at Week 16 of parent study)
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- Efficacy analyses:
  - Descriptive statistics were reported using all collected as-observed data, regardless of rescue medication use

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RESULTS
Baseline Demographics and Disease Characteristics

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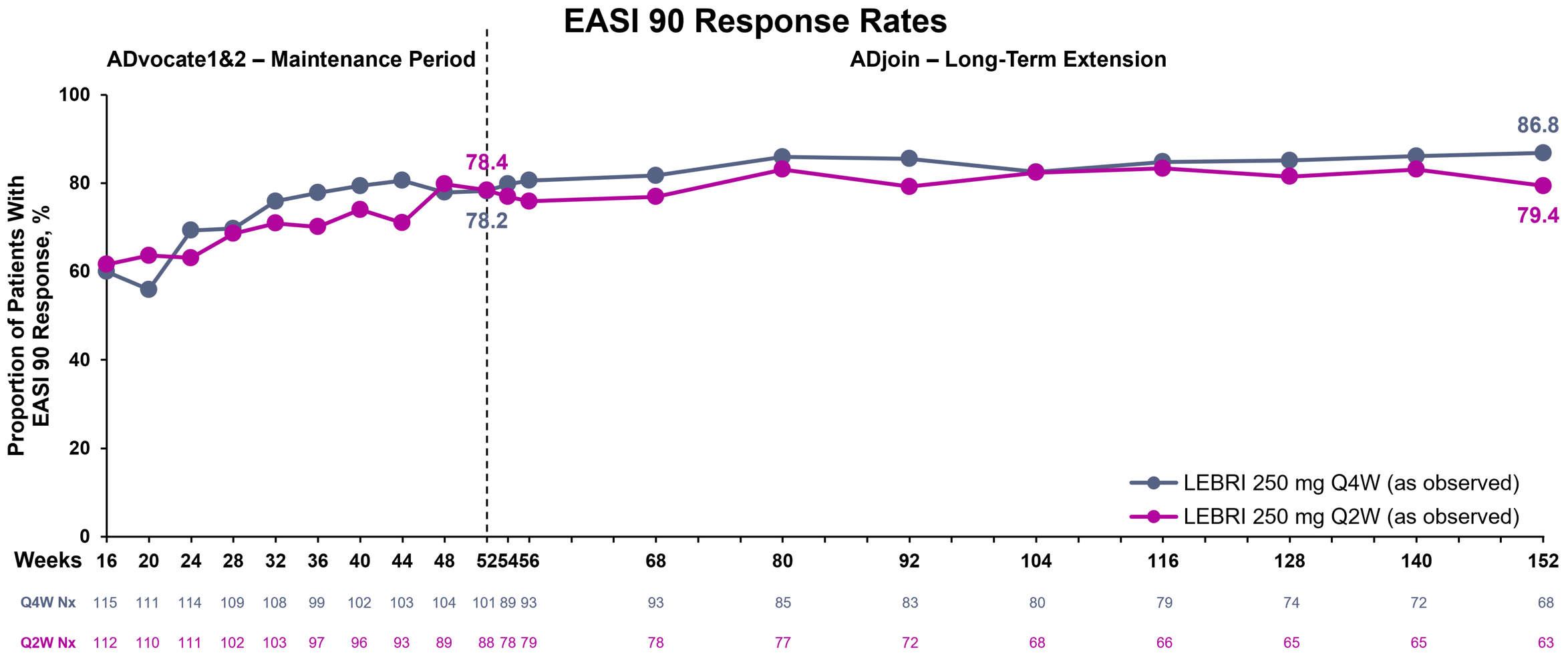
AD=atopic dermatitis; BMI=body mass index; EASI=Eczema Area and Severity Index; IGA=Investigator's Global Assessment; LEBRI=lebrikizumab; POEM=Patient-Oriented Eczema Measure; Q2W=every 2 weeks; Q4W=every 4 weeks; SD=standard deviation.

Deep Responses Were Maintained and Improved in Lebrikizumab Week 16 Responders Up to Week 152 for Both Q4W and Q2W Dosing

Note: Data from Week 16 responders achieving IGA (0,1) at Week 16 of parent study. Not all patients completing ADvocate1 and ADvocate2 were enrolled to ADjoin; Week 52 data are from ADvocate1&2 parent studies.
IGA=Investigator's Global Assessment; IGA (0)=IGA response of clear; IGA (0,1)=IGA response of clear or almost clear; LEBRI=lebrikizumab; Nx=number of patients with non-missing values; Q2W=every 2 weeks; Q4W=every 4 weeks.

Deep Responses Were Maintained and Improved in Lebrikizumab Week 16 Responders Up to Week 152 for Both Q4W and Q2W Dosing



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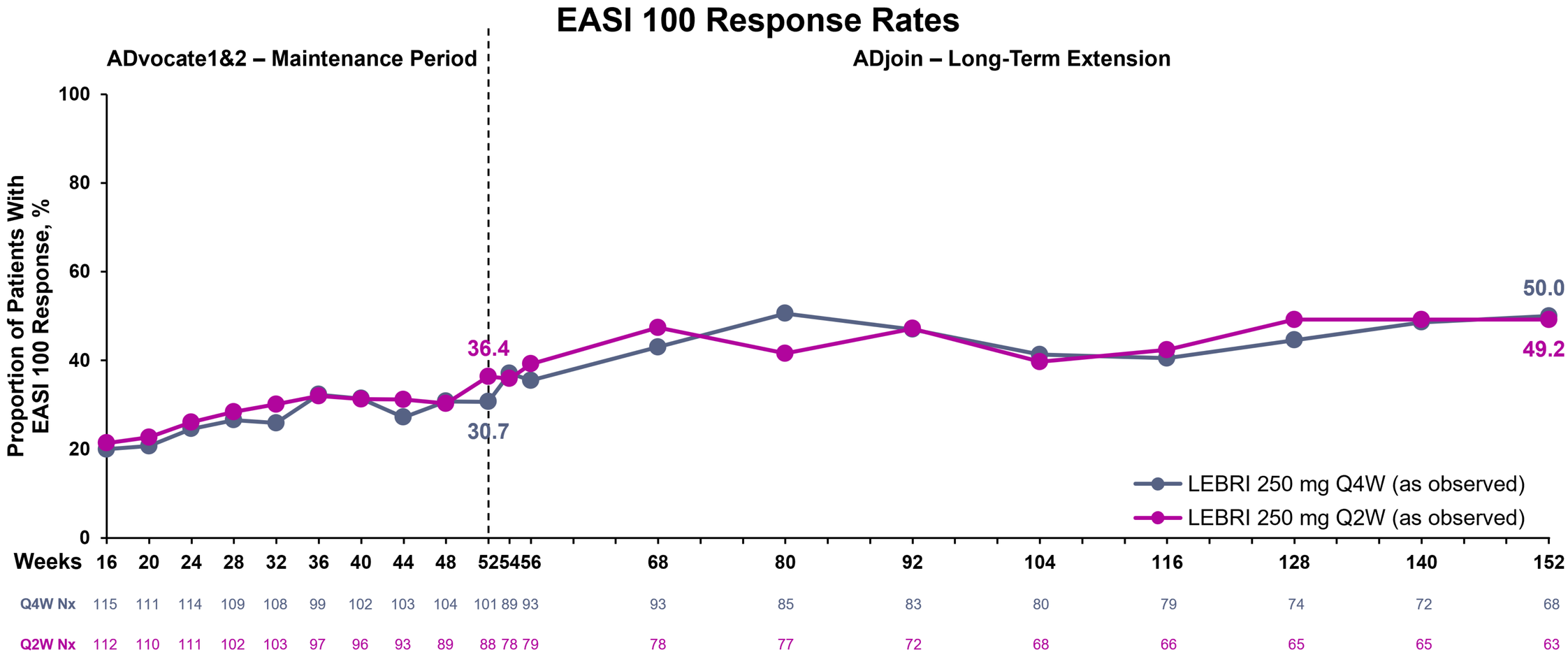
EASI=Eczema Area and Severity Index; EASI 90=at least 90% improvement from baseline in Eczema Area and Severity Index; LEBRI=lebrikizumab; Nx=number of patients with non-missing values; Q2W=every 2 weeks; Q4W=every 4 weeks.

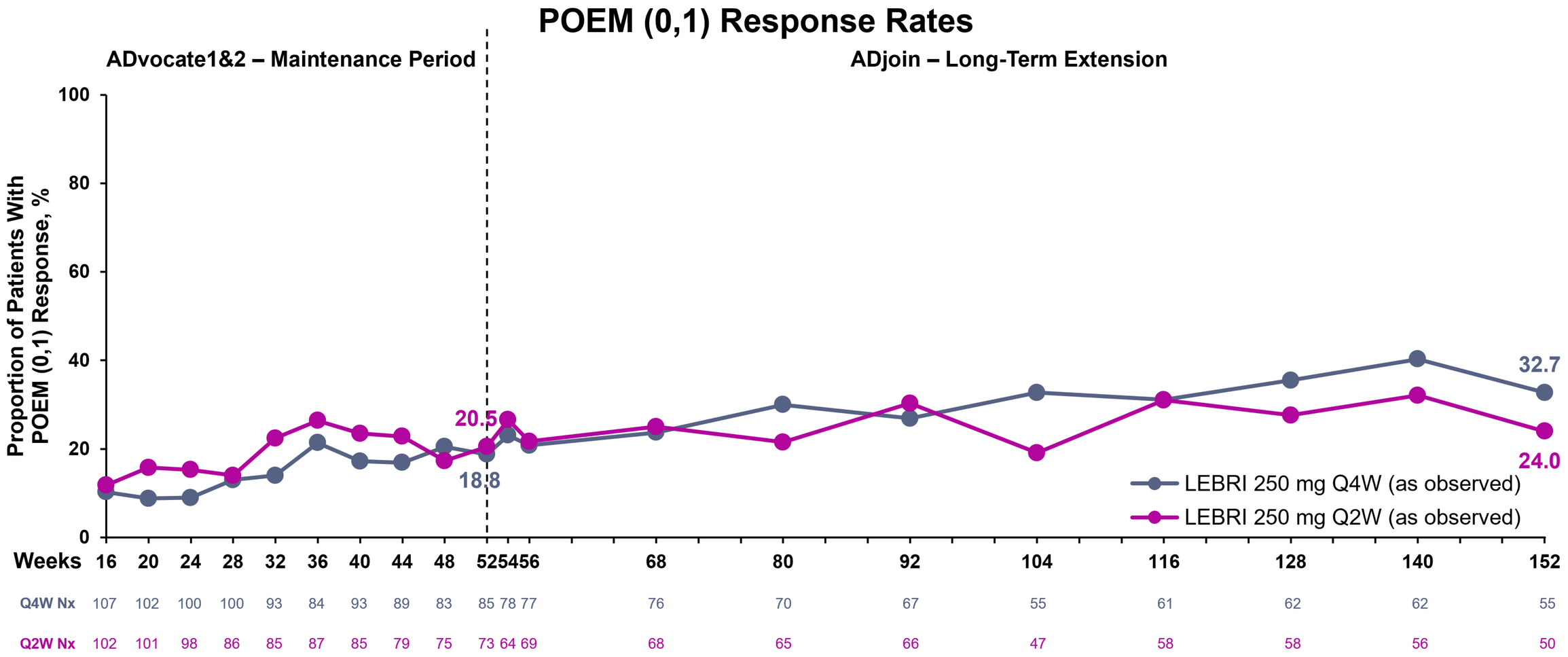
Deep Responses Were Maintained and Improved in Lebrikizumab Week 16 Responders Up to Week 152 for Both Q4W and Q2W Dosing



Note: Data from Week 16 responders achieving EASI 75 at Week 16 of parent study. Not all patients completing ADvocate1 and ADvocate2 were enrolled to ADjoin; Week 52 data are from ADvocate1&2 parent studies.

EASI=Eczema Area and Severity Index; EASI 100=100% improvement from baseline in Eczema Area and Severity Index; LEBRI=lebrikizumab; Nx=number of patients with non-missing values; Q2W=every 2 weeks; Q4W=every 4 weeks.

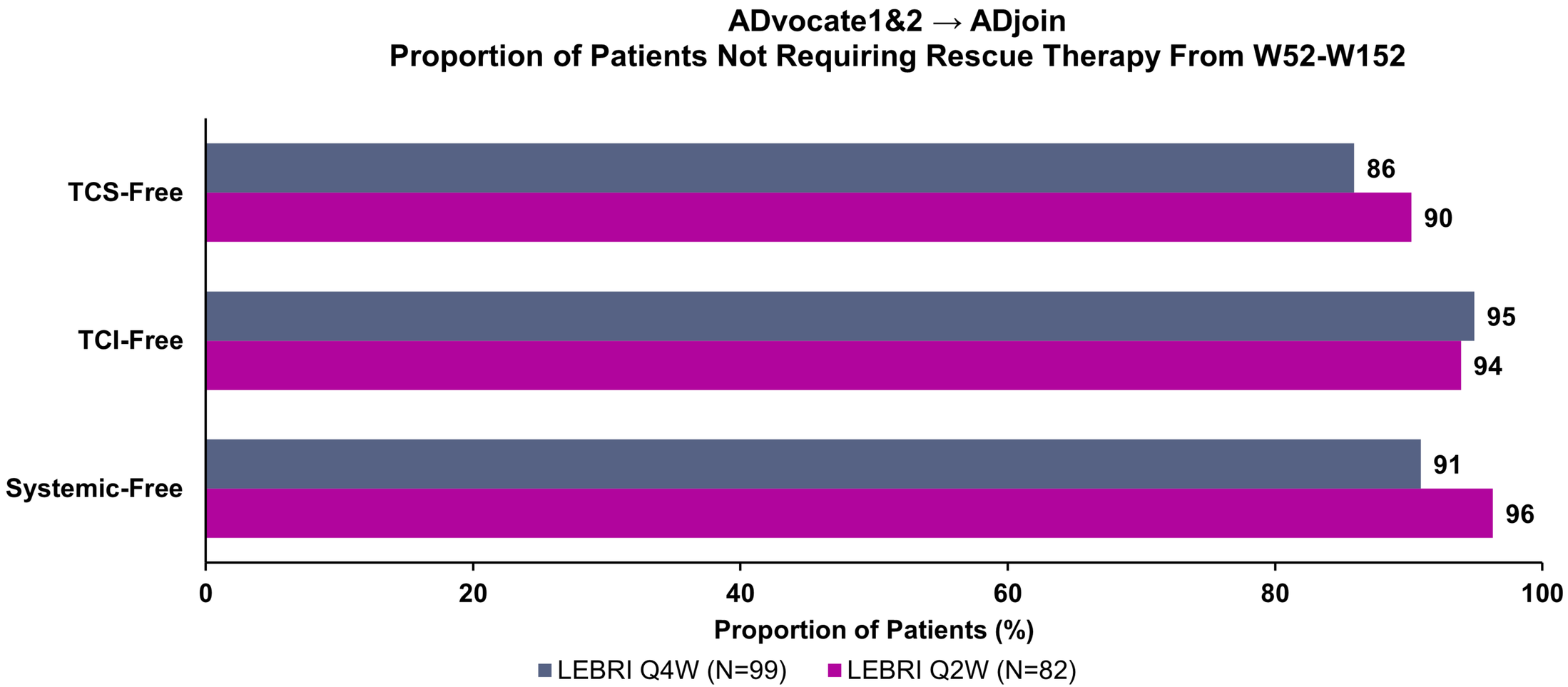
POEM (0,1) Response Was Maintained and Improved Through 152 Weeks for Both Q4W and Q2W Dosing



Note: Data from Week 16 responders of parent study. Not all patients completing ADvocate1 and ADvocate2 were enrolled to ADjoin; Week 52 data are from ADvocate1&2 parent studies.

LEBRI=lebrikizumab; Nx=number of patients with non-missing values; POEM=Patient-Oriented Eczema Measure; Q2W=every 2 weeks; Q2W=every 2 weeks; Q4W=every 4 weeks.

Most Patients Receiving Lebrikizumab Q4W and Q2W Through 152 Weeks Did Not Require Rescue Therapy[a]



[a]Rescue therapy included any topical or systemic therapy during the treatment period.
Note: Topical rescue therapy included TCS and TCIs. Systemic rescue therapy included systemic corticosteroids, immunosuppressants, biologics, phototherapy, and photochemotherapy. The majority of systemic rescue was used to treat TEAEs. Patients may have received more than 1 form of rescue therapy.
LEBRI=lebrikizumab; Q2W=every 2 weeks; Q4W=every 4 weeks; TCI=topical calcineurin inhibitor; TCS=topical corticosteroids; TEAE=treatment-emergent adverse event.

Conclusions

- Under lebrikizumab maintenance treatment in Week 16 responders, approximately 8 out of 10 achieved almost clear skin (as indicated by EASI 90) up to 3 years; additionally, over 50% of patients experienced total skin clearance, as assessed by EASI 100 or IGA (0)
- Quality of life was maintained through 3 years of continuous lebrikizumab treatment in Week 16 responders; approximately 1 out of 3 patients reported minimal to no AD-specific symptoms, as assessed by POEM (0,1), at Week 152
- Most patients did not require use of rescue therapy (TCS, TCI, or systemic treatment) with continuous lebrikizumab treatment
- These 3-year data suggest that long-term maintenance of total skin clearance is an achievable treatment goal for at least half of lebrikizumab Week 16 monotherapy responders

AD=atopic dermatitis; EASI=Eczema Area and Severity Index; EASI 90=≥90% improvement from baseline in EASI; EASI 100=100% improvement from baseline in EASI; IGA=Investigator's Global Assessment; IGA (0)=IGA response of clear; POEM=Patient-Oriented Eczema Measure; TCI=topical calcineurin inhibitor; TCS=topical corticosteroids.

References

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Abbreviations

AD=atopic dermatitis; AE=adverse event; BMI=body mass index; BSA=body surface area; EASI=Eczema Area and Severity Index; EASI 75/90/100=≥75%/≥90%/100% improvement from baseline in EASI; IGA=Investigator's Global Assessment; IGA (0)=IGA response of clear; IGA (0,1)=IGA response of clear or almost clear; LD=loading dose; LEBRI=lebrikizumab; Nx=number of patients with non-missing values; PBO=placebo; POEM=Patient-Oriented Eczema Measure; Q2W=every 2 weeks; Q4W=every 4 weeks; R=randomization; SAE=serious AE; SD=standard deviation; TCI=topical calcineurin inhibitor; TCS=topical corticosteroid; TEAE=treatment-emergent AE

Disclosures

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