P-59618

Lebrikizumab Improves Itch, Itch Interference on Sleep and Skin Pain in Patients With Moderate-to-Severe Atopic Dermatitis Previously Treated With Dupilumab

Gil Yosipovitch[1], Lindsay Ackerman[2], Jerry Bagel[3], Evangeline Pierce[4], Amber Reck Atwater[5], Maria Silk[4], Jennifer Proper[4], Sonia Montmayeur[4], Matthew Zirwas[6], Eric Simpson[7]

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OBJECTIVES

- 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[1]
- One of the other clinical questions included in the ADapt trial is:
  - How do itch, itch interference on sleep, and skin pain (eg, discomfort or soreness) change following 24 weeks of lebrikizumab treatment in patients with moderate-to-severe AD previously treated with dupilumab?

CONCLUSIONS

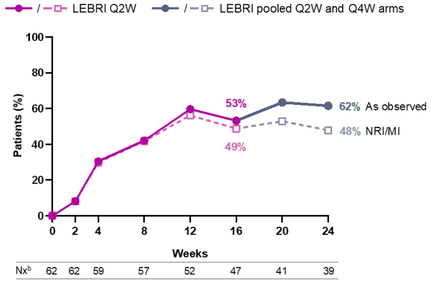
- In the ADapt trial, lebrikizumab resulted in clinically meaningful improvements in the symptoms of itch, itch interference on sleep, and skin pain in patients previously exposed to dupilumab
- Lebrikizumab provided a clinically meaningful improvement in itch response for at least half of patients who discontinued dupilumab due to inadequate response; among these patients:
  - 50.0% achieved Pruritus NRS ≥4-point improvement at Week 16
  - 65.2% achieved Pruritus NRS ≥3-point improvement at Week 16

American Academy of Dermatology (AAD); Orlando, USA; 7-11 March 2025

KEY RESULTS

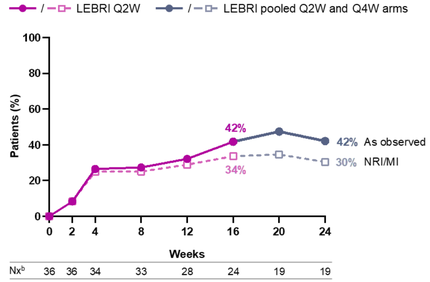
Lebrikizumab Improved Itch, Itch Interference on Sleep, and Skin Pain Throughout 24 Weeks of Treatment

Pruritus NRS ≥4-Point Improvement[a]



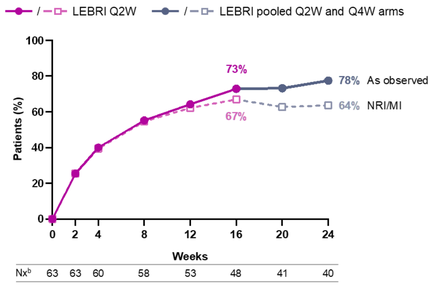
[a]ITT population with baseline Pruritus NRS ≥4; [b]As observed.
Notes: NRI/MI analyses are based on all N=62 patients at each timepoint and were performed for Week 0 to Week 24 after pooling together the LEBRI 250 mg Q2W and Q4W arms. Patients who discontinued treatment due to lack of efficacy were imputed as non-responders; all other missing data were imputed using MI.

Sleep-Loss Scale Score ≥2-Point Improvement[a]



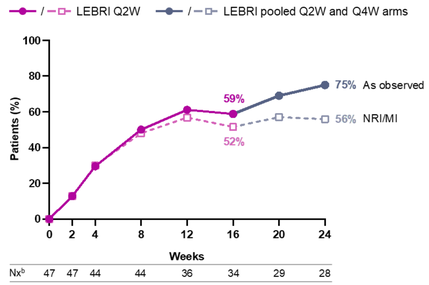
[a]ITT population with baseline Sleep-Loss Scale score ≥2; [b]As observed.
Notes: NRI/MI analyses are based on all N=36 patients at each timepoint and were performed for Week 0 to Week 24 after pooling together the LEBRI 250 mg Q2W and Q4W arms. Patients who discontinued treatment due to lack of efficacy were imputed as non-responders; all other missing data were imputed using MI.

Pruritus NRS ≥3-Point Improvement[a]



[a]ITT population with baseline Pruritus NRS ≥3; [b]As observed.
Notes: NRI/MI analyses are based on all N=63 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.

Skin Pain ≥4-Point Improvement[a]



[a]ITT population with baseline Skin Pain ≥4; [b]As observed.
Notes: NRI/MI analyses are based on all N=47 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.

RESULTS

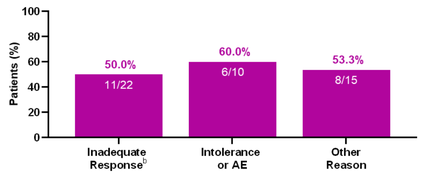
Baseline Demographics and Disease Characteristics

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)
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)
Sleep-Loss Scale score	1.9 (1.0)	1.8 (1.1)	2.1 (1.0)	1.9 (1.1)
≥2, n (%)	36 (51.4)	17 (45.9)	7 (58.3)	12 (57.1)
Skin Pain	5.5 (2.9)	5.5 (2.9)	6.1 (3.0)	5.1 (2.9)
≥4, n (%)	47 (68.1)	23 (62.2)	10 (83.3)	14 (70.0)
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)
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)
Number of prior systemic treatments,[b] 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 (20.8)
≥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, and previous open-label clinical trial participation that completed with no discontinuation for AEs; [b]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.

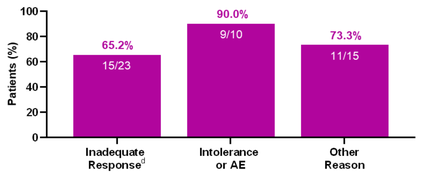
Achievement of Pruritus NRS Improvement at Week 16 by Reason for Prior Dupilumab Discontinuation

Pruritus NRS ≥4-Point[a]



[b]Of these 11 patients, 1 was from the group of patients with no response to dupilumab (Nx=3), 5 were from the group of patients with partial response to dupilumab (Nx=13), and 5 were from the group of patients who had lost response to dupilumab (Nx=6)

Pruritus NRS ≥3-Point[c]



[d]Of these 15 patients, 3 were from the group of patients with no response to dupilumab (Nx=3), 7 were from the group of patients with partial response to dupilumab (Nx=14), and 5 were from the group of patients who had lost response to dupilumab (Nx=6)

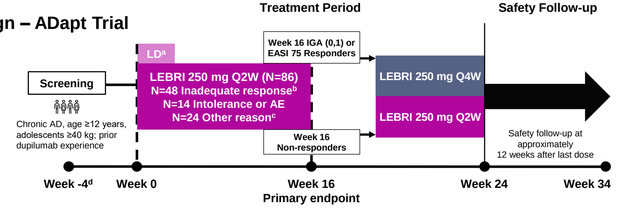
[a]ITT population with baseline Pruritus NRS ≥4; [c]ITT population with baseline Pruritus NRS ≥3.
Notes: 47 patients with baseline Pruritus NRS ≥4 and 48 patients with baseline Pruritus NRS ≥3 had observed data at Week 0 and Week 16 and were included in this subgroup analysis. Data inside the bars are n/Nx. Reasons for dupilumab discontinuation were patient-reported. The 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, 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.

BACKGROUND

- Variable patient responses to biologics have been demonstrated in AD[1]
- Given the heterogeneity and dynamic nature of AD[2], patients may respond differently to lebrikizumab and dupilumab
- While lebrikizumab and dupilumab both inhibit IL-13 signaling, there are differences in their pharmacokinetics and mechanisms of action[3-6]

METHODS

Study Design – ADapt Trial



[a]Patients received an LD of 500 mg given SC at Week 0 and Week 2; [b]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; [c]Other reasons included being unable to afford treatment, health insurance changes, and previous open-label clinical trial participation that completed with no discontinuation for adverse events; [d]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.

Outcomes

- Proportions of patients achieving the following outcomes were reported from Week 0 through Week 24:
  - Pruritus NRS[a] ≥4-point and ≥3-point improvement from baseline[b]
  - Sleep-Loss Scale[c] score ≥2-point improvement from baseline[d]
  - Skin Pain NRS[e] ≥4-point improvement from baseline[f]
- Pruritus NRS ≥4-point and ≥3-point improvement from baseline at Week 16 by reason for prior dupilumab discontinuation was also reported[b]

[a]A patient-reported, single-item, 11-point scale used daily to rate worst itch severity over the past 24 hours (0 indicates "no itch"; 10 indicates "worst itch imaginable")[1]; [b]Among patients with baseline Pruritus NRS ≥4 and ≥3, respectively; [c]A patient-reported, single-item, 5-point Likert scale used daily to rate the extent of sleep loss due to interference of itch over the last night (0 indicates "not at all"; 4 indicates "unable to sleep at all")[1]; [d]Among patients with baseline Sleep-Loss Scale score ≥2; [e]A patient-reported, 11-point horizontal scale used daily to rate worst level of skin pain (eg, discomfort or soreness) in the past 24 hours (0 indicates "no pain"; 10 indicates "worst pain imaginable")[1]; [f]Among patients with baseline Skin Pain NRS ≥4.

Abbreviations: *AD=atopic dermatitis; AE=adverse event; BSA=body surface area; 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; ITT=intent-to-treat; JAK=Janus kinase; LD=loading dose; LEBRI=lebrikizumab; MI=multiple imputation; 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; SC=subcutaneous; SD=standard deviation; TCI=topical calcineurin inhibitor; TCS=topical corticosteroids*

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This study was funded by 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.

Supplemental Materials
Scan the QR code for additional Methods and Results

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BACKGROUND AND OBJECTIVES

Background

- Variable patient responses to biologics have been demonstrated in AD[1]
- Given the heterogeneity and dynamic nature of AD[2], patients may respond differently to lebrikizumab and dupilumab
- While lebrikizumab and dupilumab both inhibit IL-13 signaling, there are differences in their pharmacokinetics and mechanisms of action[3-6]

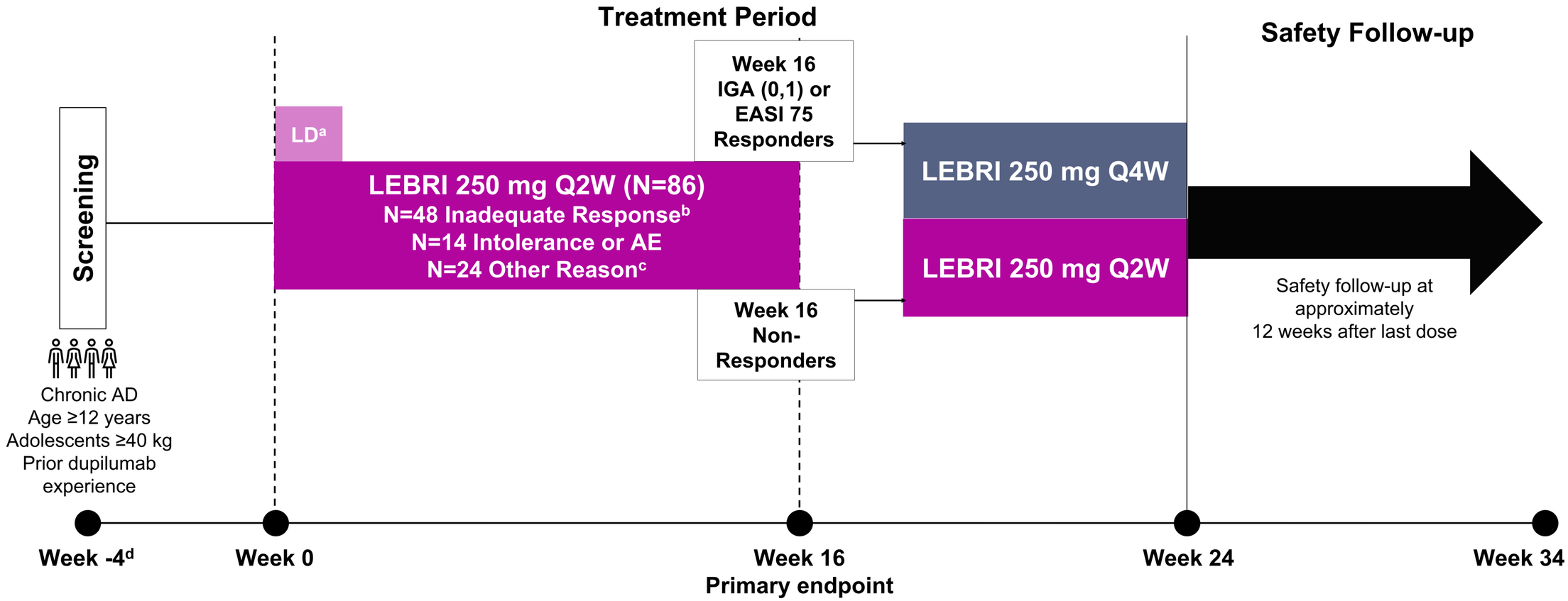
Objectives

- 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[1]
- One of the other clinical questions included in the ADapt trial is:
  - How do itch, itch interference on sleep, and skin pain (eg, discomfort or soreness) change following 24 weeks of lebrikizumab treatment in patients with moderate-to-severe AD previously treated with dupilumab?

AD=atopic dermatitis.

METHODS – Study Design

ADapt Trial



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Outcomes

- Proportions of patients achieving the following outcomes were reported from Week 0 through Week 24:
  - Pruritus NRS[a] ≥4-point and ≥3-point improvement from baseline[b]
  - Sleep-Loss Scale[c] score ≥2-point improvement from baseline[d]
  - Skin Pain NRS[e] ≥4-point improvement from baseline[f]
- Pruritus NRS ≥4-point and ≥3-point improvement from baseline at Week 16 by reason for prior dupilumab discontinuation was also reported[b]

[a]A patient-reported, single-item, 11-point scale used daily to rate worst itch severity over the past 24 hours (0 indicates “no itch”; 10 indicates “worst itch imaginable”)[7]; [b]Among patients with baseline Pruritus NRS ≥4 and ≥3, respectively; [c]A patient-reported, single-item, 5-point Likert scale used daily to rate the extent of sleep loss due to interference of itch over the last night (0 indicates “not at all”; 4 indicates “unable to sleep at all”)[8]; [d]Among patients with baseline Sleep-Loss Scale score ≥2; [e]A patient-reported, 11-point horizontal scale used daily to rate worst level of skin pain (eg, discomfort or soreness) in the past 24 hours (0 indicates “no pain”; 10 indicates “worst pain imaginable”)[9]; [f]Among patients with baseline Skin Pain NRS ≥4.

NRS=Numeric Rating Scale.

RESULTS – Baseline Demographics and Disease Characteristics (1/2)

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)
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)
Sleep-Loss Scale score	1.9 (1.0)	1.8 (1.1)	2.1 (1.0)	1.9 (1.1)
≥2, n (%)	36 (51.4)	17 (45.9)	7 (58.3)	12 (57.1)
Skin Pain NRS	5.5 (2.9)	5.5 (2.9)	6.1 (3.0)	5.1 (2.9)
≥4, n (%)	47 (68.1)	23 (62.2)	10 (83.3)	14 (70.0)

[Table continues on the next slide. Table will appear as one in the poster]

[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, and previous open-label clinical trial participation that completed with no discontinuation for AEs.
Notes: Data are mean (SD) unless stated otherwise. Number of patients with non-missing data was used as the denominator.
AE= event; LEBRI=lebrikizumab; NRS=Numeric Rating Scale; SD=standard deviation.

RESULTS – Baseline Demographics and Disease Characteristics (2/2)

Characteristic	All LEBRI (N=86)	Reason for Dupilumab Discontinuation[a]		
		Inadequate Response (N=48)	Intolerance or AE (N=14)	Other Reason (N=24)
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)
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)
Number of prior systemic treatments,[b] 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 (20.8)
≥3	14 (16.3)	8 (16.7)	4 (28.6)	2 (8.3)

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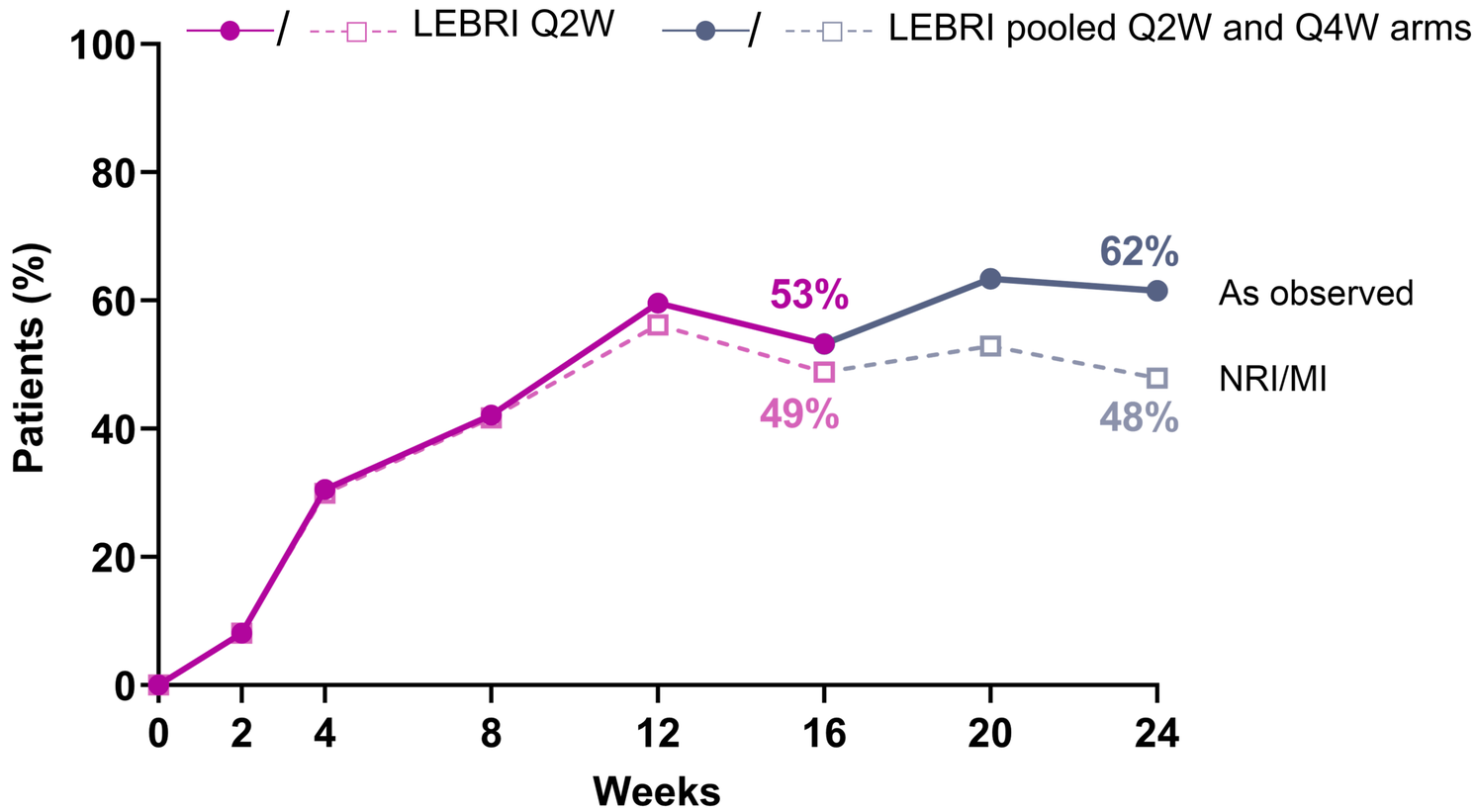
Notes: Data are mean (SD) unless stated otherwise. Number of patients with non-missing data was used as the denominator.

BSA=body surface area; EASI=Eczema Area and Severity Index; IGA=Investigator's Global Assessment; LEBRI=lebrikizumab; SD=standard deviation.

Lebrikizumab Improved Itch, Itch Interference on Sleep, and Skin Pain Throughout 24 Weeks of Treatment (1/4)

Pruritus NRS ≥4-Point Improvement[a]



Nx[b]	62	62	59	57	52	47	41	39

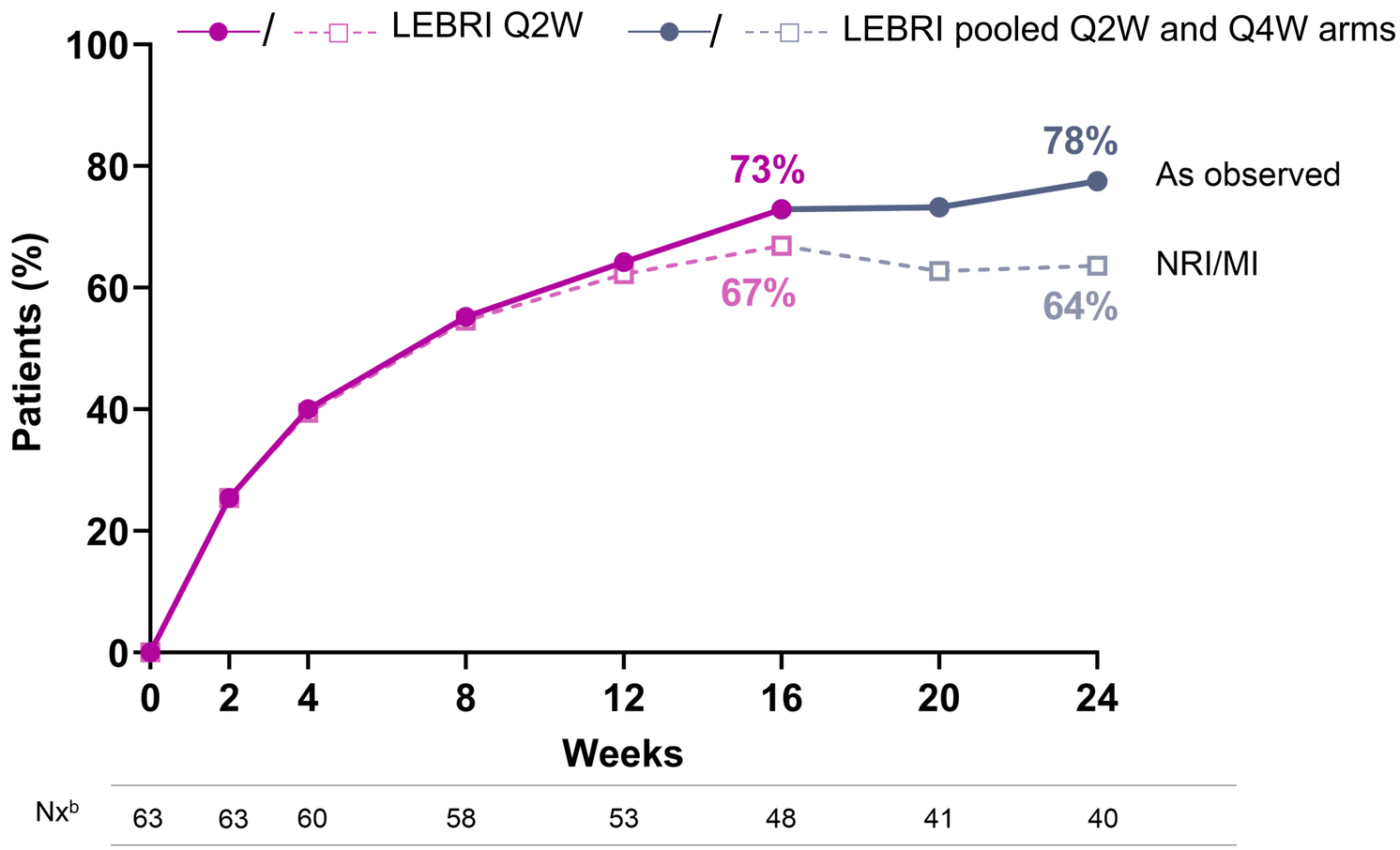
[a]ITT population with baseline Pruritus NRS ≥4; [b]As observed.

Notes: NRI/MI analyses are based on all 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.

ITT=intent-to-treat; LEBRI=lebrikizumab; MI=multiple imputation; NRI=non-responder imputation; NRS=Numeric Rating Scale; Nx=number of patients with non-missing values; Q2W=every 2 weeks; Q4W=every 4 weeks.

Lebrikizumab Improved Itch, Itch Interference on Sleep, and Skin Pain Throughout 24 Weeks of Treatment (2/4)

Pruritus NRS ≥3-Point Improvement[a]



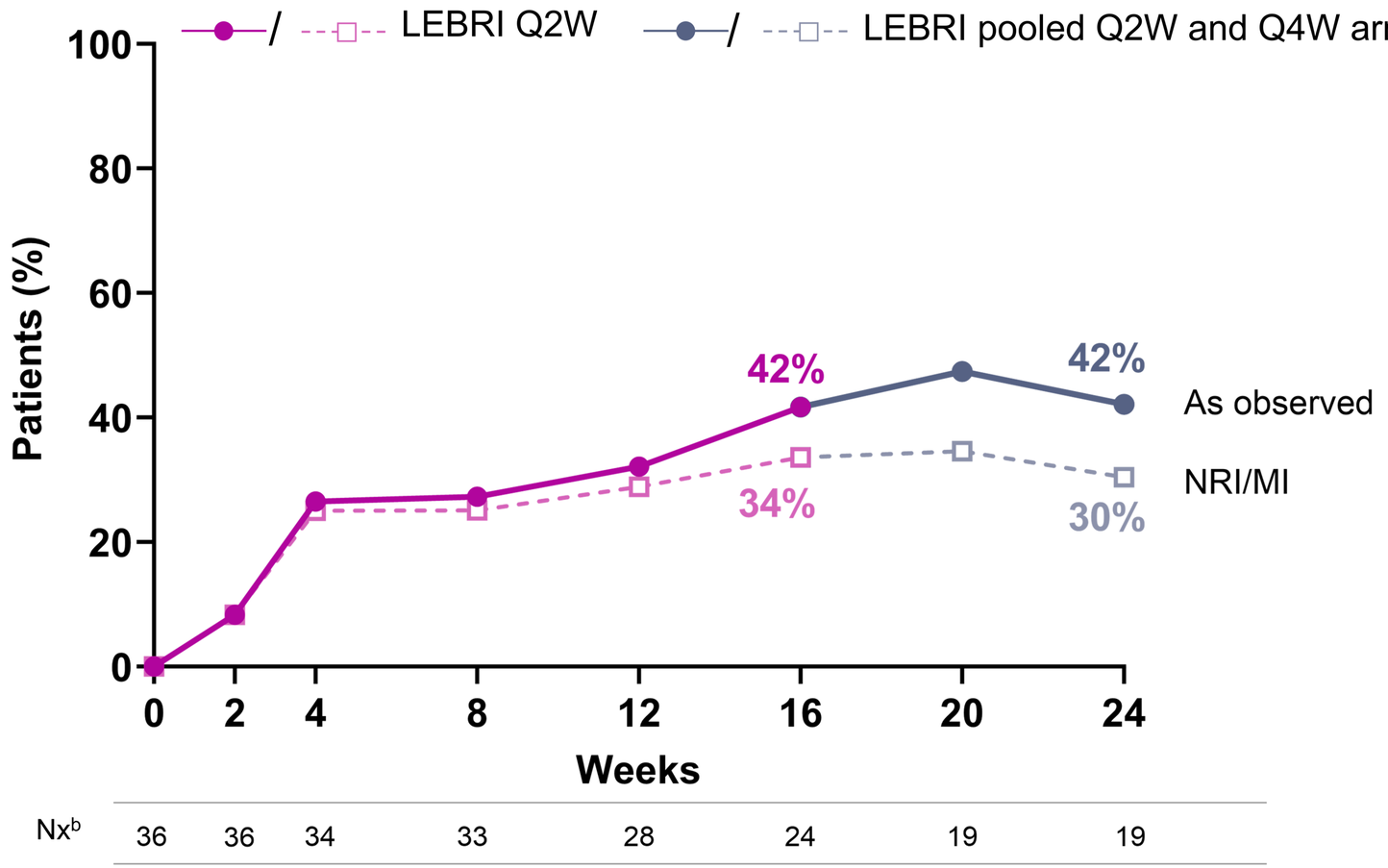
[a]ITT population with baseline Pruritus NRS ≥3; [b]As observed.

Notes: NRI/MI analyses are based on all N=63 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.

ITT=intent-to-treat; LEBRI=lebrikizumab; MI=multiple imputation; NRI=non-responder imputation; NRS=Numeric Rating Scale; Nx=number of patients with non-missing values; Q2W=every 2 weeks; Q4W=every 4 weeks..

Lebrikizumab Improved Itch, Itch Interference on Sleep, and Skin Pain Throughout 24 Weeks of Treatment (3/4)

Sleep-Loss Scale Score ≥2-Point Improvement[a]



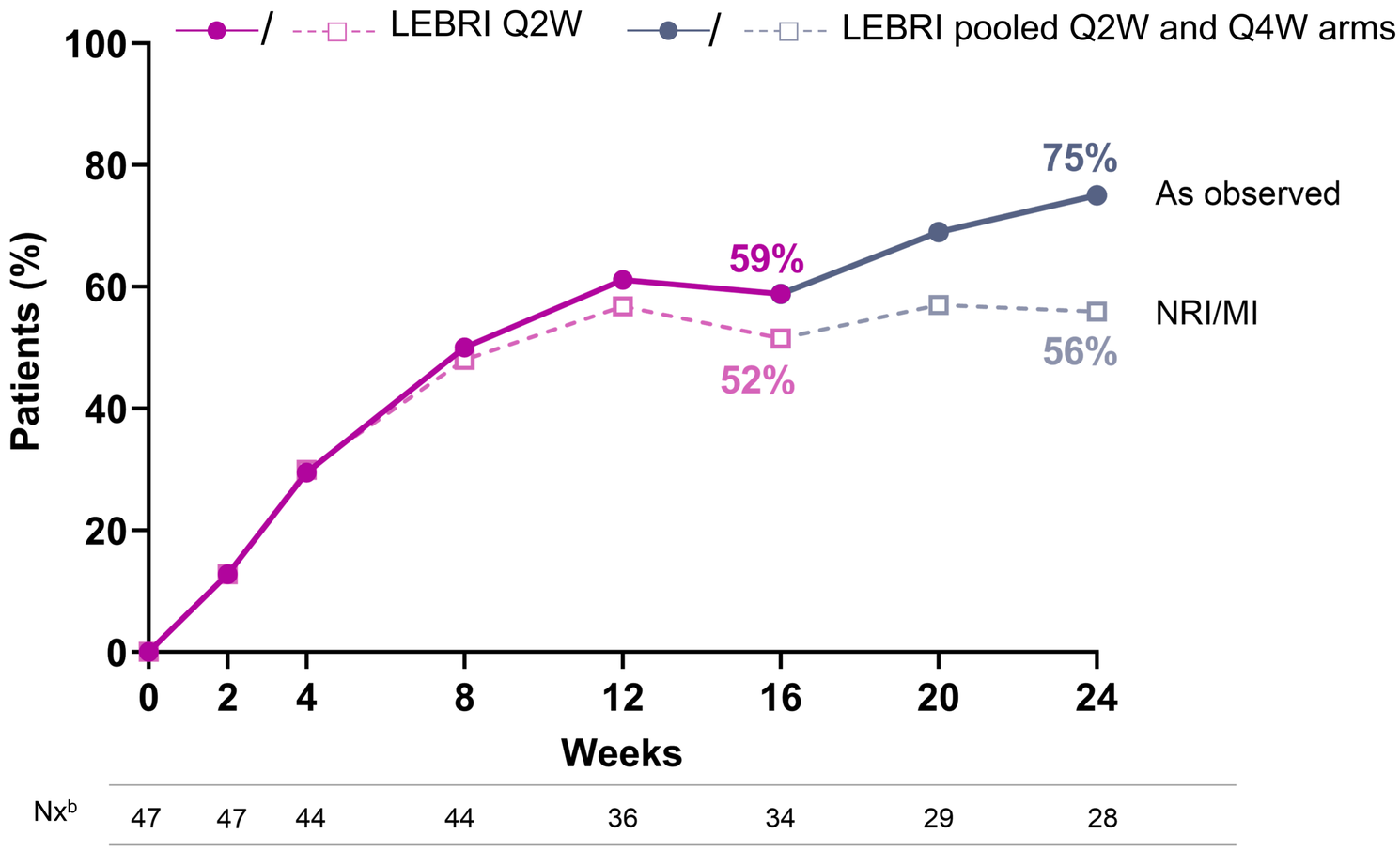
[a]ITT population with baseline Sleep-Loss Scale score ≥2; [b]As observed.

Notes: NRI/MI analyses are based on all N=36 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.

ITT=intent-to-treat; LEBRI=lebrikizumab; MI=multiple imputation; NRI=non-responder imputation; Nx=number of patients with non-missing values; Q2W=every 2 weeks; Q4W=every 4 weeks..

Lebrikizumab Improved Itch, Itch Interference on Sleep, and Skin Pain Throughout 24 Weeks of Treatment (4/4)

Skin Pain ≥4-Point Improvement[a]



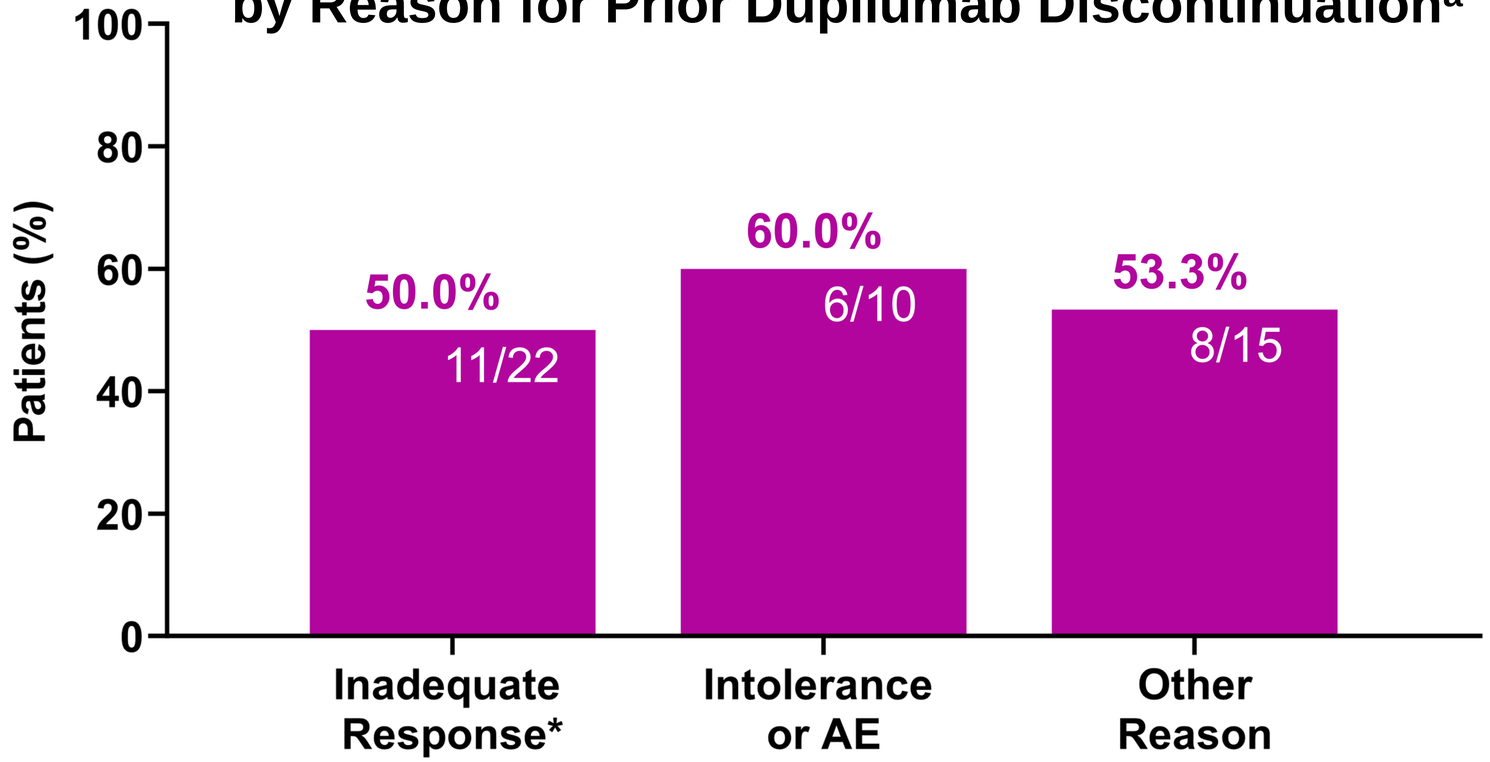
[a]ITT population with baseline Skin Pain ≥4; [b]As observed.

Notes: NRI/MI analyses are based on all N=47 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.

ITT=intent-to-treat; LEBRI=lebrikizumab; MI=multiple imputation; NRI=non-responder imputation; Nx=number of patients with non-missing values; Q2W=every 2 weeks; Q4W=every 4 weeks..

How are Patients With Inadequate Response to Dupilumab Likely to Respond to Lebrikizumab? (1/2)

Achievement of Pruritus NRS ≥4-Point Improvement at Week 16 by Reason for Prior Dupilumab Discontinuation[a]



* Of these 11 patients, 1 was from the group of patients with no response to dupilumab (Nx=3), 5 were from the group of patients with partial response to dupilumab (Nx=13), and 5 were from the group of patients who had lost response to dupilumab (Nx=6)

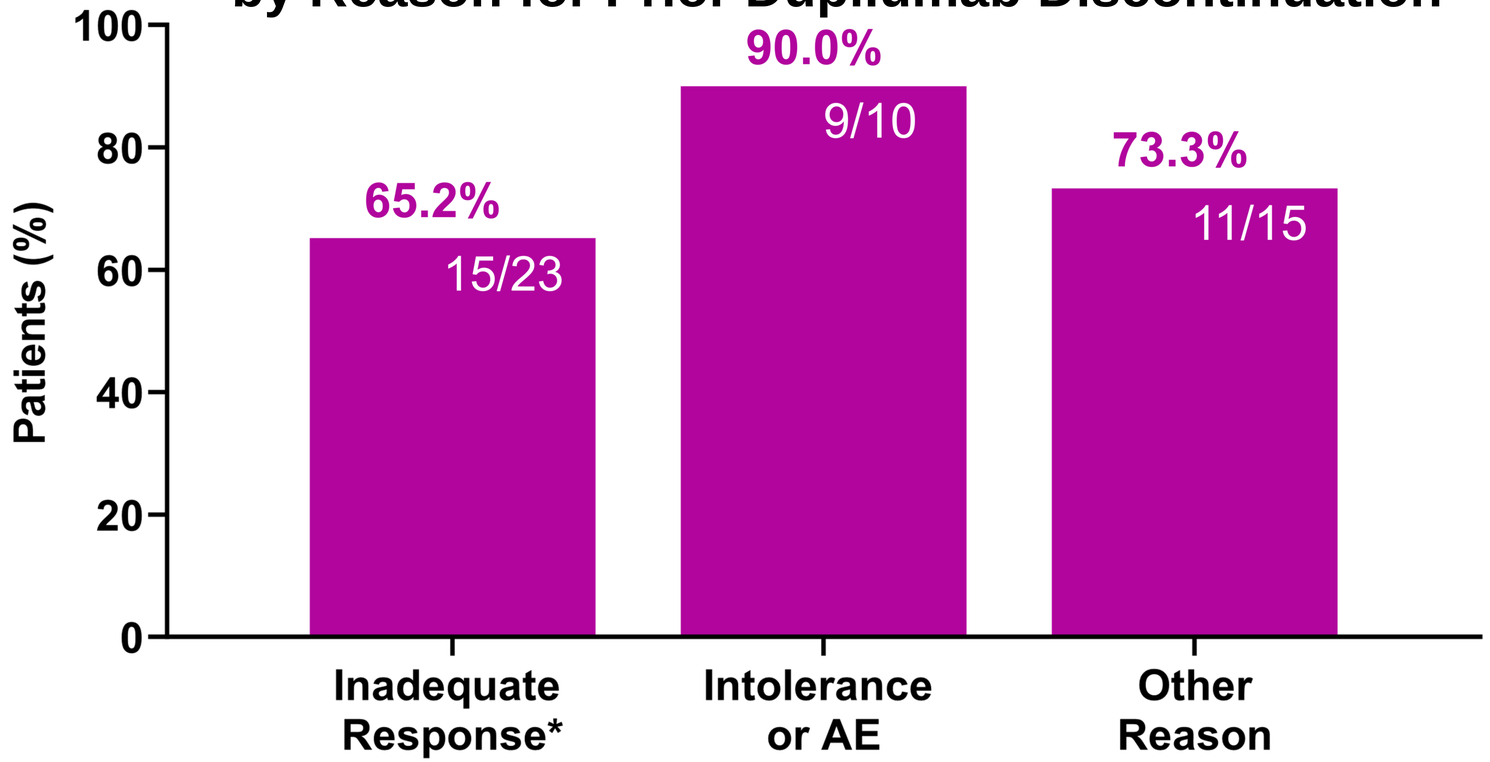
[a]ITT population with baseline Pruritus NRS ≥4.

Notes: 47 patients with baseline Pruritus NRS ≥4 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 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, 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.

AE=adverse event; ITT=intent-to-treat; NRS=Numeric Rating Scale; Nx=number of patients with non-missing values.

How are Patients With Inadequate Response to Dupilumab Likely to Respond to Lebrikizumab? (2/2)

Achievement of Pruritus NRS ≥3-Point Improvement at Week 16 by Reason for Prior Dupilumab Discontinuation[a]



* Of these 15 patients, 3 were from the group of patients with no response to dupilumab (Nx=3), 7 were from the group of patients with partial response to dupilumab (Nx=14), and 5 were from the group of patients who had lost response to dupilumab (Nx=6)

[a]ITT population with baseline Pruritus NRS ≥3.

Notes: 48 patients with baseline Pruritus NRS ≥3 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 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, 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.

AE=adverse event; ITT=intent-to-treat; NRS=Numeric Rating Scale; Nx=number of patients with non-missing values.

CONCLUSIONS

- In the ADapt trial, lebrikizumab resulted in clinically meaningful improvements in the symptoms of itch, itch interference on sleep, and skin pain in patients previously exposed to dupilumab
- Lebrikizumab provided a clinically meaningful improvement in itch response for at least half of patients who discontinued dupilumab due to inadequate response; among these patients:
  - 50.0% achieved Pruritus NRS ≥4-point improvement at Week 16
  - 65.2% achieved Pruritus NRS ≥3-point improvement at Week 16

NRS=Numeric Rating Scale.

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Abbreviations

AD=atopic dermatitis; AE=adverse event; BSA=body surface area; 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; ITT=intent-to-treat; JAK=Janus kinase; LD=loading dose; LEBRI=lebrikizumab; MI=multiple imputation; 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; SC=subcutaneous; SD=standard deviation; TCI=topical calcineurin inhibitor; TCS=topical corticosteroids

Disclosures

G. Yosipovitch has conducted clinical trials for or received research funds and/or honoraria for serving on the scientific advisory boards of: AbbVie, Arcutis, Eli Lilly and Company, Escient Pharmaceuticals, Galderma, Kiniksa Pharmaceuticals, LEO Pharma, Novartis, Pfizer, Regeneron, and Sanofi; **L. Ackerman** has received honoraria as an advisory board member, consultant, and/or speaker and served as an investigator for: AbbVie, Amgen, Apollo Therapeutics, argenx; AstraZeneca, Biofrontera, Bristol Myers Squibb, Castle Biosciences, ChemoCentryx, CorEvitas, Corrona, DermTech, Eli Lilly and Company, Exact Sciences, GlaxoSmithKline, Helsinn Healthcare, IgGenix, Incyte Corporation, Janssen, Kymera Therapeutics, Kyowa Kirin, LEO Pharma, Lilly ICOS, Mindera, Novartis, Regeneron, Replimune, Sanofi, Sun Pharma, Takeda, Timber Pharmaceuticals, Trevi Therapeutics, and UCB Pharma; **J. Bagel** has received research funds payable to the Psoriasis Treatment Center of New Jersey from: AbbVie, Amgen, Arcutis, Boehringer Ingelheim, Brickell Biotech, Bristol Myers Squibb, Celgene, Corrona, Dermavant, Dermira, Eli Lilly and Company, Janssen, Kadmon Corporation, LEO Pharma, Menlo Therapeutics, Mindera, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, TARGET PharmaSolutions, Taro Pharmaceutical Industries, UCB Pharma, and Valeant Pharmaceuticals; and has received consultant fees or speaker fees from: AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Incyte Corporation, Janssen, Mindera, Novartis, and UCB Pharma; **E. Pierce**, **M. Silk**, **J. Proper**, **S. Montmayeur**, and **M. Zirwas** are employees and shareholders of: Eli Lilly and Company; **A. Reck Atwater** is a former employee of: Eli Lilly and Company; **E. Simpson** reports personal fees from: AbbVie, Advances in Cosmetic Medical Dermatology Hawaii, Amgen, AOBiome, Arcutis, Arena Pharmaceuticals, ASLAN Pharmaceuticals, Bristol Myers Squibb, CorEvitas, Dermira, Eli Lilly and Company, Evelo Biosciences, Excerpta Medica, FIDE, Forte Biosciences, Galderma, GlaxoSmithKline, Impetus Healthcare, Incyte Corporation, Innovaderm Research, Janssen, Johnson & Johnson, Kyowa Kirin, LEO Pharma, Maui Derm, Medscape, Merck, MJH Holding, MLG Operating, Pfizer, Physicians World, PRImE, Recludix Pharma, Regeneron, Revolutionizing Atopic Dermatitis, Roivant 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, CorEvitas, Dermira, Dermavant, Eli Lilly and Company, Incyte Corporation, Kymab, Kyowa Kirin, National Jewish Health, LEO Pharma, Pfizer, Regeneron, Sanofi, Target, and VeriSkin. These potential conflicts of interest have been reviewed and managed by Oregon Health & Science University

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P-59618

SUPPLEMENTAL MATERIALS
Lebrikizumab Improves Itch, Itch Interference on Sleep and Skin Pain in Patients With Moderate-to-Severe Atopic Dermatitis Previously Treated With Dupilumab

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[1]University of Miami Miller School of Medicine, Miami, USA, [2]U.S. Dermatology Partners, Phoenix, USA, [3]Schwweiger Dermatology Group, East Windsor, USA, [4]Eli Lilly and Company, Indianapolis, USA, [5]Distinctive Dermatology, Great Valls, USA, [6]Dermatologists of the Central States, Probity Medical Research, and Ohio University, Bexley, USA, [7]Oregon Health & Science University, Portland, USA

This study was funded by 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.

Key Eligibility Criteria

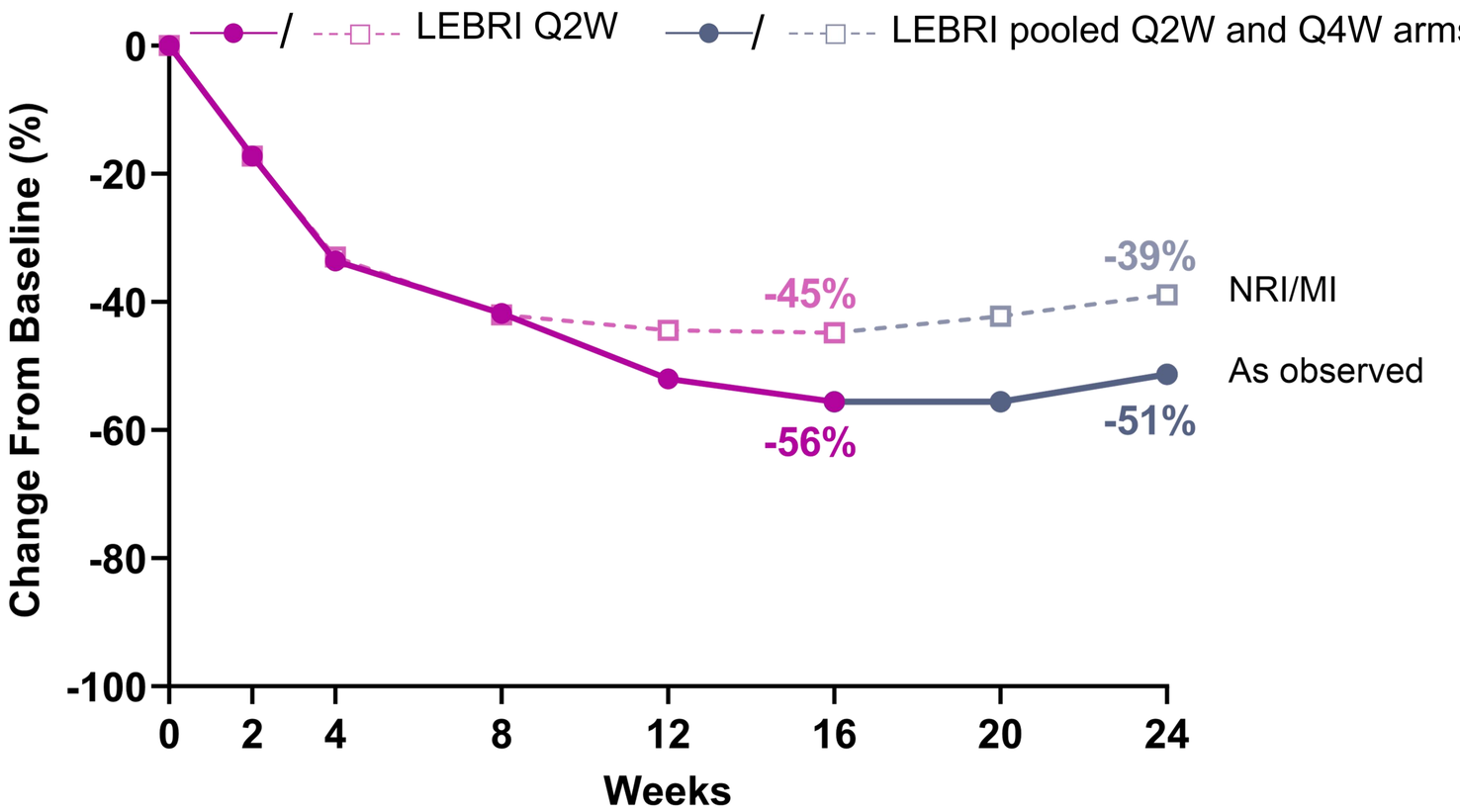
- Adults (≥18 years) and adolescents (≥12 to <18 years; weight ≥40 kg)
- Ceased treatment with dupilumab[a] due to:
  - Inadequate response: non-response, partial response, or loss of efficacy at labeled dose level for ≥4 months
  - Intolerance or AEs
  - Other reasons
- Chronic AD for ≥1 year
- Moderate-to-severe AD, including baseline:
  - EASI[b,c] ≥16
  - IGA[c,d] ≥3
  - BSA involvement[c,e] ≥10%
- History of inadequate response to topical medications

[a]≥4 weeks before baseline; [b]A composite index with scores ranging from 0 to 72, with higher values indicating more severe and/or extensive disease; [c]Investigators received training and certification; [d]A 5-point scale that provides a global clinical assessment of AD severity ranging from 0 to 4, where 0 indicates clear, 1 is almost clear, 2 is mild, 3 is moderate, and 4 indicates severe AD; [e]Assessment to estimate the extent of disease or skin involvement, expressed as a percentage of total body surface and reported by body location.

AD=atopic dermatitis; AE=adverse event; BSA=body surface area; EASI=Eczema Area and Severity Index; IGA=Investigator's Global Assessment.

Lebrikizumab Improved Itch Throughout 24 Weeks of Treatment

Pruritus NRS Change From Baseline[a]



Nx[b]	70	70	67	64	58	53	46	45

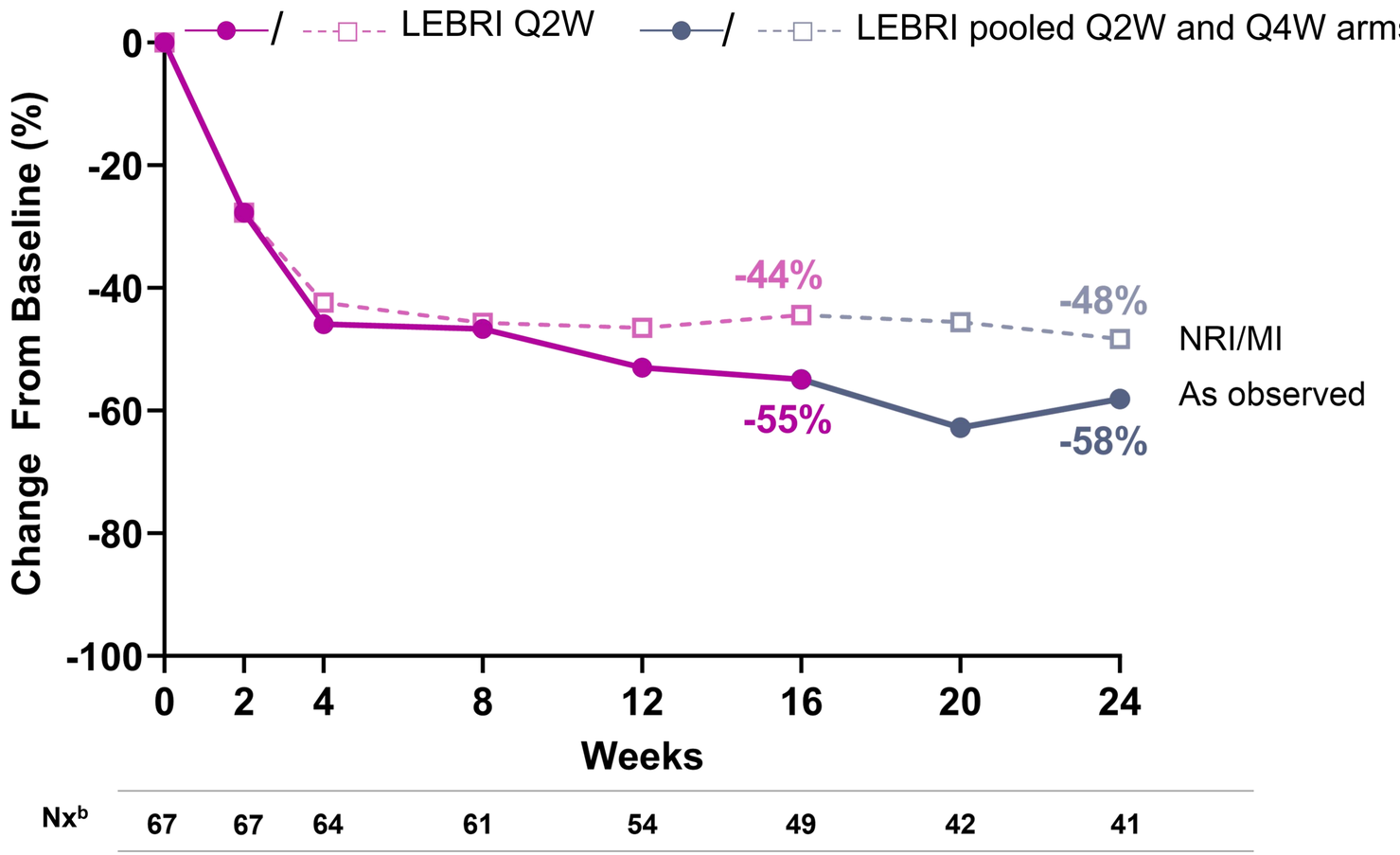
[a]ITT population with baseline Pruritus NRS; [b]As observed.

Notes: NRI/MI analyses are based on all N=70 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.

ITT=intent-to-treat; LEBRI=lebrikizumab; MI=multiple imputation; NRI=non-responder imputation; NRS=Numeric Rating Scale; Nx=number of patients with non-missing values; Q2W=every 2 weeks; Q4W=every 4 weeks.

Lebrikizumab Improved Itch Interference on Sleep Throughout 24 Weeks of Treatment

Sleep-Loss Scale Change From Baseline[a]



[a]ITT population with baseline Sleep-Loss Scale score; [b]As observed.

Notes: NRI/MI analyses are based on all N=67 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.

ITT=intent-to-treat; LEBRI=lebrikizumab; MI=multiple imputation; NRI=non-responder imputation; Nx=number of patients with non-missing values; Q2W=every 2 weeks; Q4W=every 4 weeks..