



Lebrikizumab ADvocate 1 & 2

16 week data

30th March 2022



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30th March 2022

Agenda

1. Introduction

Atopic dermatitis market

Gianfranco Nazzi, CEO

2. Lebrikizumab & Atopic Dermatitis

Biologics & the IL-13 pathway

Lebrikizumab, the science

ADvocate 1 & 2 study design

Phase 3, week 16 data

Karl Ziegelbauer, CSO

3. Closing Remarks

Gianfranco Nazzi, CEO



Introduction



Dermatology, an attractive medical and commercial space

Atopic dermatitis market potential analog to Psoriasis market



Atopic dermatitis (AD) is an underserved and growing market.



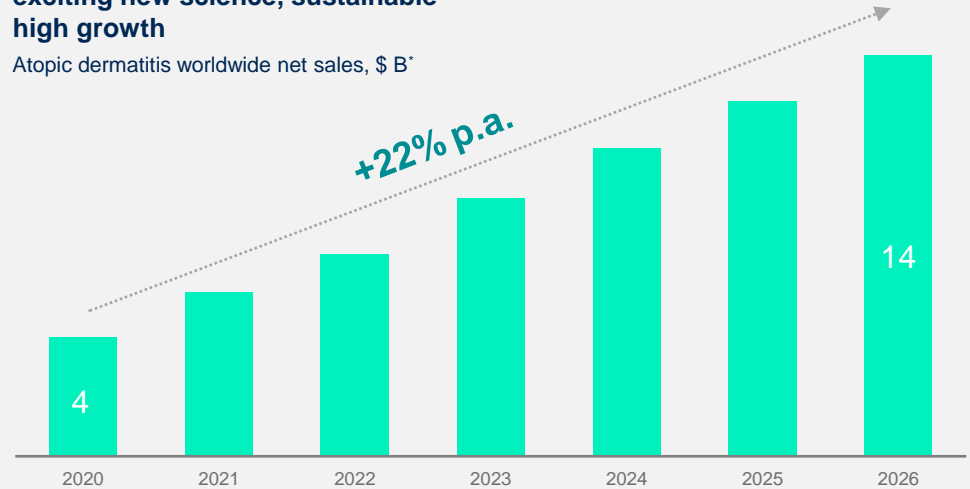
AD market is growing at 22% CAGR. Our innovative product Lebrikizumab is on track for a 2023 potential EU approval, with new biologics becoming the standard of care.



Large AD market opportunity is driven by the advent of new systemic therapies in context of a large prevalent population with substantial unmet need.

Multiple severe unmet needs, exciting new science, sustainable high growth

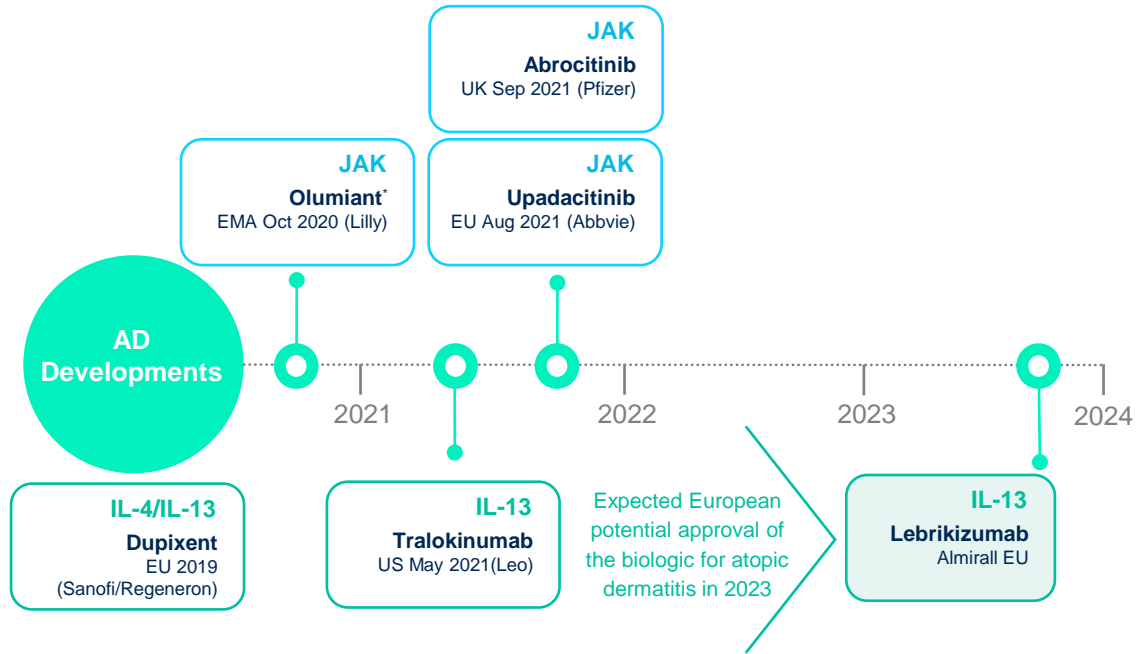
Atopic dermatitis worldwide net sales, \$ B*



* Net sales are based on Evaluate Pharma's indication-specific sales which are indicative of market expectations and have a degree of uncertainty.

Developments in the AD market

Lebrikizumab to be the third biologic to market



* Olumiant approved in the EMA (Oct 2020) and Japan (Dec 2020), the FDA has extended the review period for the supplemental New Drug Application.

Compelling profile

Primary & all key secondary endpoints met in pivotal phase 3 studies

Compelling efficacy profile:

significant improvements with >50% of people treated achieved at least 75% improvement in overall disease severity (EASI-75) at week 16.

Clinically meaningful improvements

in itch and other important patient-reported outcomes achieved as compared to those patients taking placebo.

Fast onset of action

with Lebrigizumab rapidly improved skin and itch symptoms **within four weeks.**

Phase 3 study confirms

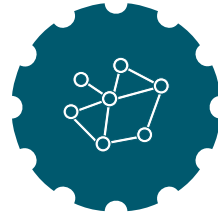
Lebrigizumab may potentially offer a compelling combination of efficacy and safety.

Lebrikizumab: Statistically significant improvements in skin clearance and itching versus placebo

Improvements in interference of itch on sleep and quality of life



Lebrikizumab delivered rapid improvements in skin clearance, itch and quality-of-life measures for those with moderate-to-severe atopic dermatitis.



Data reinforce our belief that Lebrikizumab represents the new generation of biologics in atopic dermatitis.



We believe 52-week results from ADvocate 1 & 2 will further highlight that Lebrikizumab can provide much needed relief for people who struggle from this chronic life-long disease.

All data compared in clinical trial versus placebo.

Lebrikizumab 16 week phase 3 data



Lebrikizumab & Atopic Dermatitis

AD is a chronic, inflammatory skin disease characterized by intractable pruritus

Atopic dermatitis is a chronic, relapsing skin disease characterized by intense itching, dry skin and inflammation that can be present on any part of the body.¹



AD is a heterogeneous disease both biologically and clinically and may be characterized by a highly variable appearance in which flares occur in an unpredictable manner.¹



Like other chronic inflammatory diseases, AD is immune-mediated and involves a complex interplay of immune cells and inflammatory cytokines.²



Moderate-to-severe AD is characterized by intense itching, which leads to an itch-scratch cycle that further damages the skin.³



People living with AD often report symptoms of intense, persistent itch which can be so uncomfortable that it can affect sleep, daily activities and social relationships.

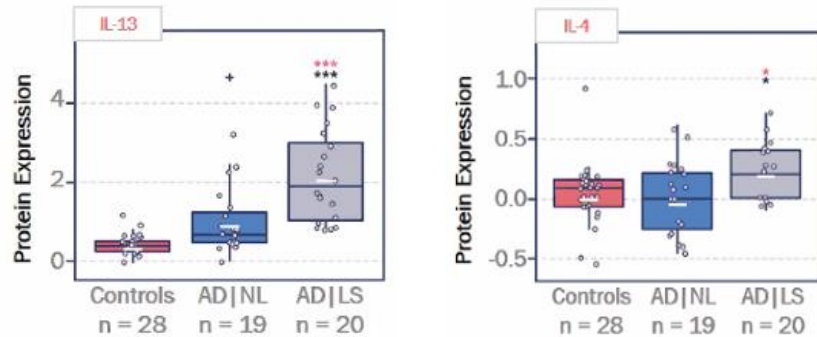
Atopic dermatitis is an underserved and growing market

¹ Weidinger S, Novak N. Lancet. 2016;387:1109-1122. ² Langan SM, et al. Arch Dermatol. 2008;142:1109. ³ Zhu R, et al. Pulm Pharmacol Ther. 2017;46:88-98.

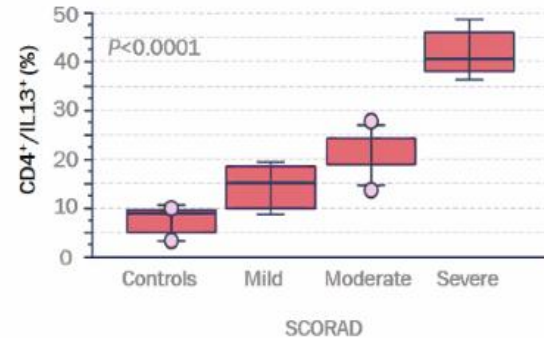
IL-13 is the key driver of TH2 inflammation in Atopic Dermatitis

- 1 IL-13 has a dominant role in lesional skin of AD patients and correlates with AD severity^{1,2}
- 2 IL-4 was nearly undetectable in lesional skin^{2,3} and its therapeutic relevance in AD is unclear^{4,5}

IL-13 vs IL-4 expression in skin



IL-13 expression correlates with disease severity



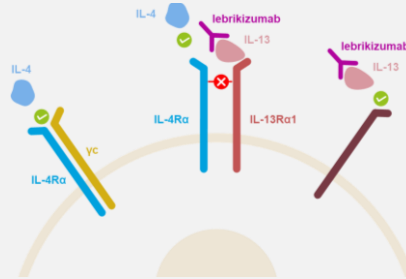
Adapted from Pavel et al, American Dermat 2020 Mar 82(3): 690-699, presented at ISDS Nov2021. 1. Renert-Yuval (2021) JACI 147:1174. 2 Pavel (2020) JAAD 82:690. 3 Tsoi (2019) J Invest Dermatol 139:1480. 4 Bieber (2020) Allergy 75:54. 5 Chiricozzi (2020) Immunotargets Ther 9:151.

AD: Atopic Dermatitis; NL: non-lesional; IL13: Interleukine 13; CD: cluster of differentiation; CD4+: T helper cells.

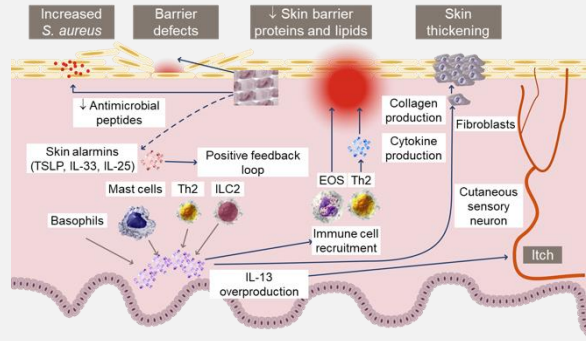
Lebrikizumab 16 week phase 3 data

Lebrikizumab binds to IL-13 with high affinity

Lebrikizumab Mechanism of Action



Sources and impact of IL-13 in skin



1

Lebrikizumab prevents the signaling of IL-13 through the heterodimeric receptor (IL-4Ra/IL-13Ra1)^{1,2}.

2

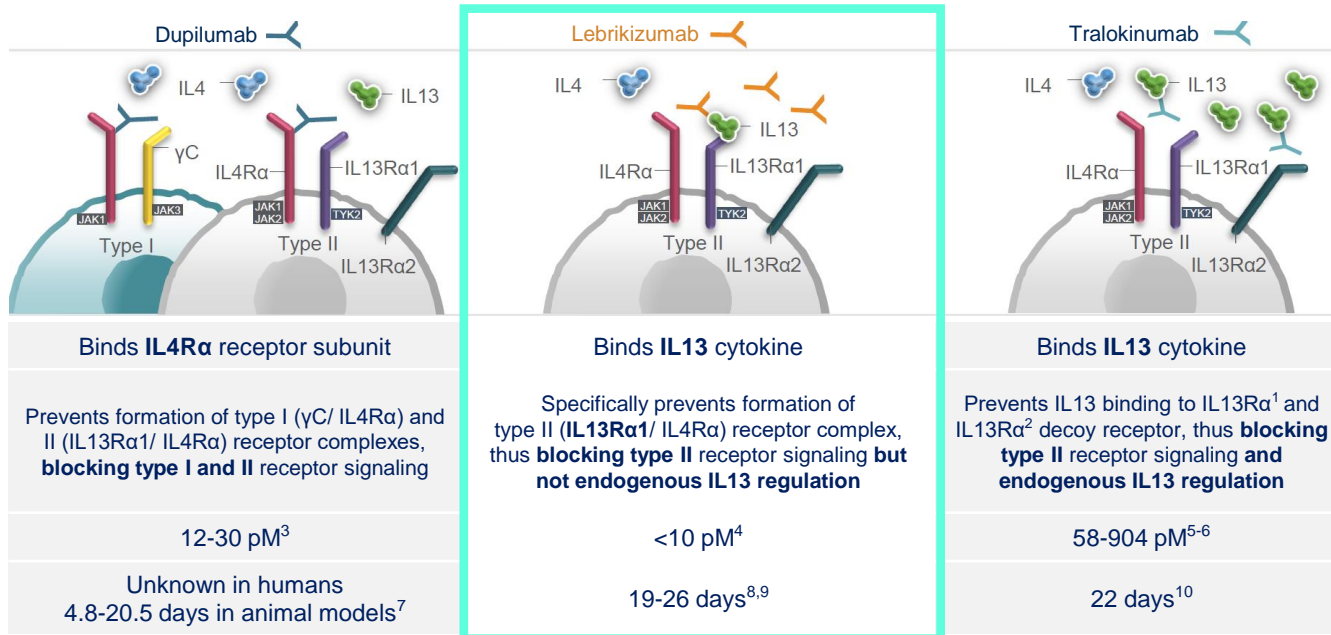
Lebrikizumab/IL-13 complex can bind to the IL-13Ra2 receptor, without interfering the endogenous regulation of the IL-13 cytokine³.

3

Lebrikizumab has a high bioavailability.

¹ Simpson EL, et al. J Am Acad Dermatol. 2018;78:863-871.e11. ² Gonçalves F, et al. Drugs Context. 2021;10:2021-1-7. ³ Wulur I, et al. Presented at 4th Inflammatory Skin Disease Summit. 2021. AD=atopic dermatitis; EOS=eosinophil; IL=interleukin; ILC2=type 2 innate lymphoid cell; S. aureus=Staphylococcus aureus; Th2 cell=type 2 helper cell; TSLP=thymic stromal lymphopoietin.

Lebrikizumab has a different mode of action than other approved biologics for atopic dermatitis



¹ Roy (2002) J Leukoc Biol 72:580. ² Juntilla(2008) J Exp Med 205:2595. ³ FDA (2018) Dupilumab clinical pharmacology review, 12/6/16. ⁴ Ultsch (2013) J Mol Bio 425:1330. ⁵ Popovic B, et al. J Mol Biol. 2017;429:208-219. ⁶ Okragly A, et al. Poster presented at Inflammatory Skin Disease Summit (ISDS); 2021. Poster 89. ⁷ Dupixent EMA Assessment Report, 2017. Data from rodents and primates. ⁸ Simpson EL, et al. J Am Acad Dermatol. 2018;78(5):863-871.e11. ⁹ Zhu R, et al. Pulm Pharmacol Ther. 2017;46:88-98. ¹⁰ Adtralza [SmPC]. Ballerup, Denmark: LEO Pharma A/S, 2021.

ADvocate 1 & 2 study

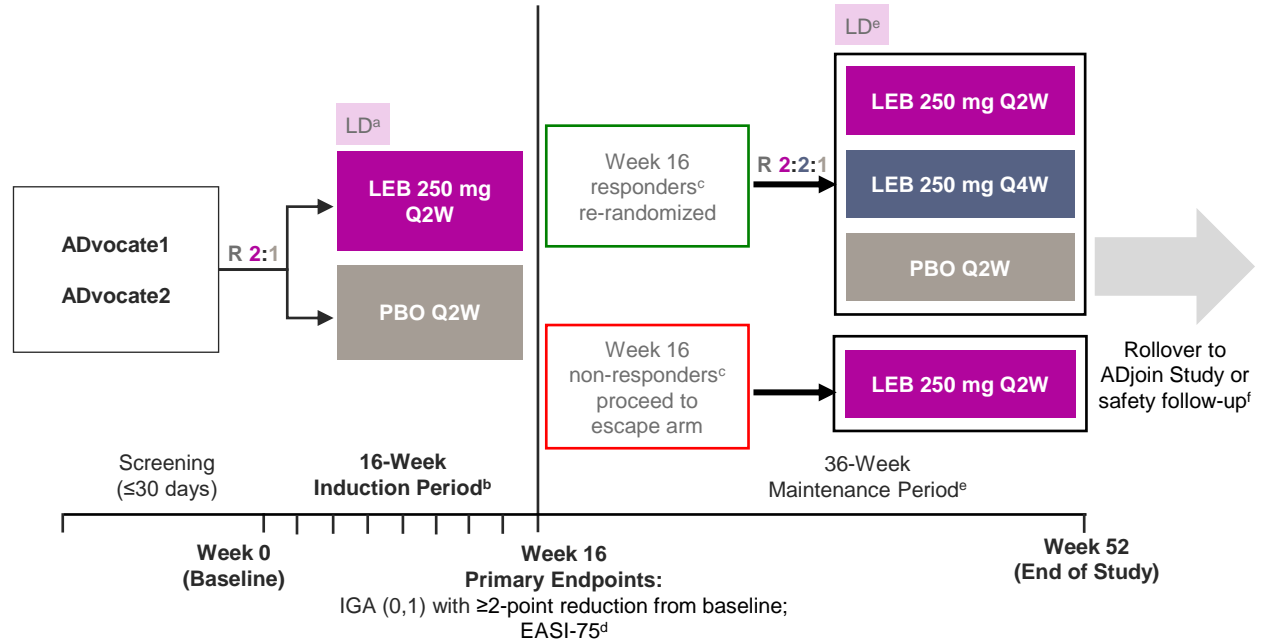
Designed to evaluate Lebrikizumab as monotherapy in adult & adolescent patients with moderate-to-severe atopic dermatitis

Co-Primary endpoints:

- IGA 0/1 + ≥ 2 points of improvement from baseline at week 16
- EASI-75 at week 16

Key secondary endpoints:

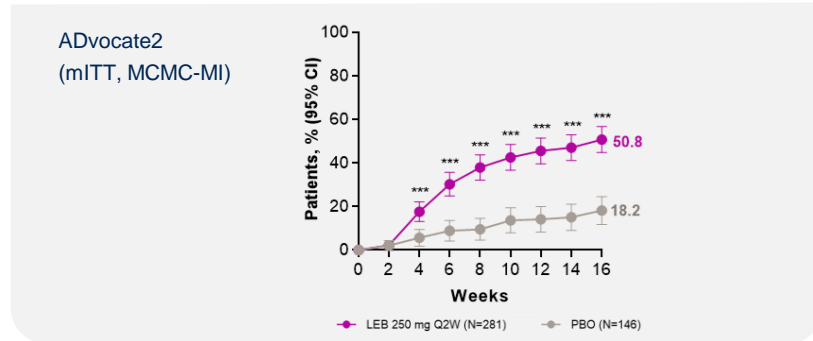
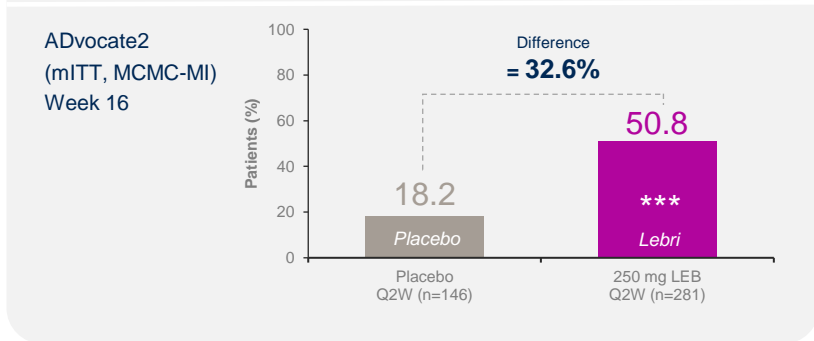
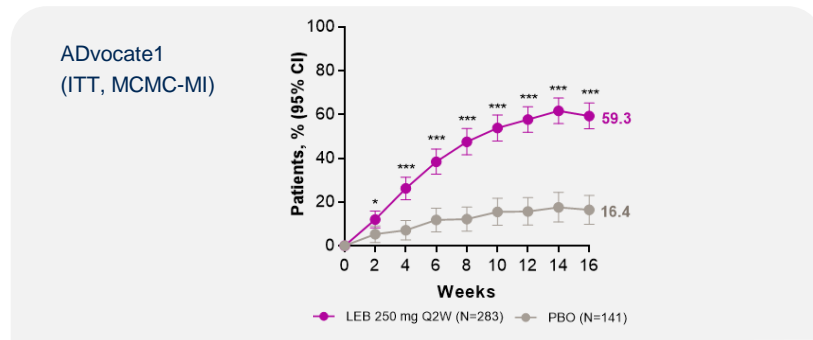
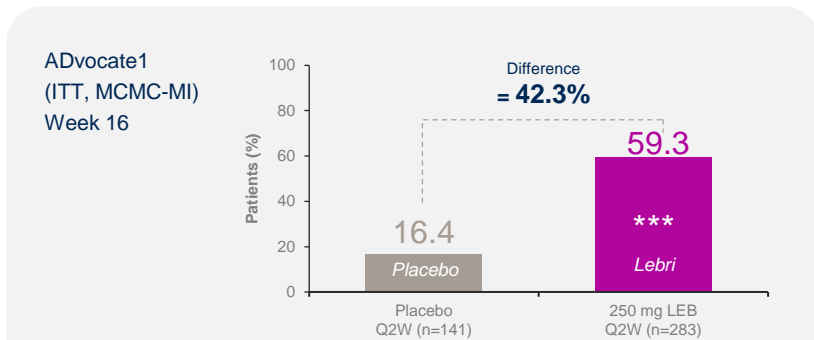
- ≥ 4 points improvement from BL in pruritus NRS at weeks 16; 4; 2
- EASI-90 at week 16
- DLQI; sleep loss at week 16



Note: Only data from the 16-week Induction Period are presented. ^a LEB-treated patients received a 500-mg LD at Weeks 0 and 2. ^b Patients who used rescue therapy (including topical) during the Induction Period were considered to be non-responders. ^c Responders were patients who achieved an IGA response of 0,1 or EASI-75 at Week 16. ^d EASI-75 was identified as a co-primary endpoint by European regulators and as a major secondary endpoint by the FDA. ^e Responders who received PBO and were re-randomized to LEB received an LD of LEB 500 mg at Week 16 or at Weeks 16 and 18, based on the active treatment group assigned in the Maintenance Period. ^f Patients who completed the study were offered treatment in ADjoin; otherwise, patients participated in a safety follow-up 12 weeks after their last dose. AD=atopic dermatitis; EASI=Eczema Area and Severity Index; EASI-75=75% reduction from baseline in EASI score; FDA=US Food and Drug Administration; LD=loading dose; LEB=lebrikizumab; PBO=placebo; Q2W=every 2 weeks; Q4W=every 4 weeks; R=randomization.

Primary Endpoint EASI-75

>50% of the patients achieved at least 75% improvement in overall disease severity



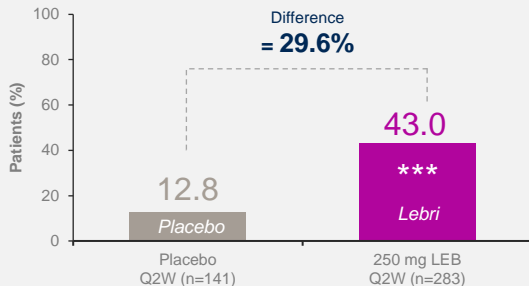
* p<0.05; ** p<0.01; *** p<0.001 vs. PBO based on the Cochran-Mantel-Haenszel test stratified by geographic region (US vs. Europe vs. rest of world), age (adolescents 12 to <18 years old vs. adults ≥18 years old), and disease severity (baseline IGA score of 3 vs. 4). Missing data as a result of rescue medication or treatment discontinuation due to lack of efficacy were imputed with baseline values; missing data due to other reasons were imputed with MCMC-MI within treatment arms. CI=confidence interval; EASI=Eczema Area and Severity Index; EASI-75=75% reduction from baseline in EASI score; ITT=Intent-to-Treat; LEB=lebrikizumab; MCMC-MI=Markov Chain Monte Carlo multiple imputation; mITT=modified ITT; PBO=placebo; Q2W=every 2 weeks.



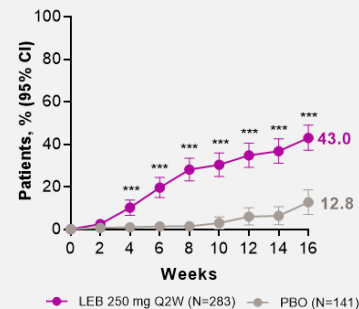
Primary Endpoint IGA

IGA patient response rate as early as week 4

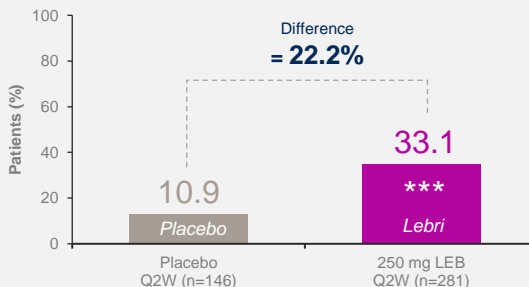
ADvocate1
(ITT, MCMC-MI)
Week 16



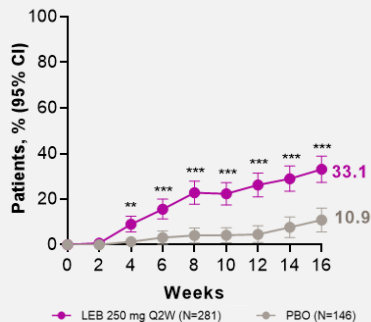
ADvocate1
(ITT, MCMC-MI)



ADvocate2
(mITT, MCMC-MI)
Week 16



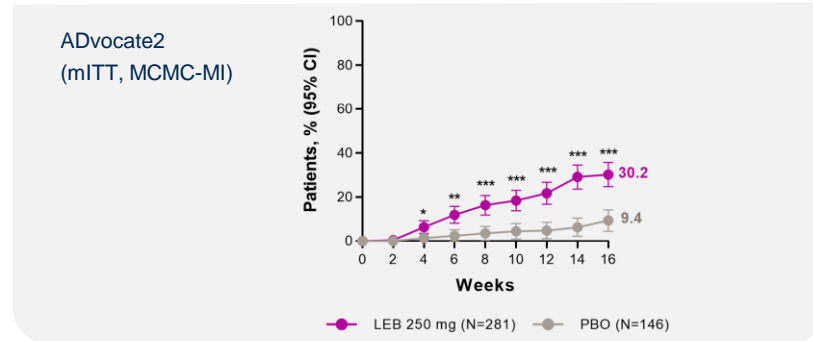
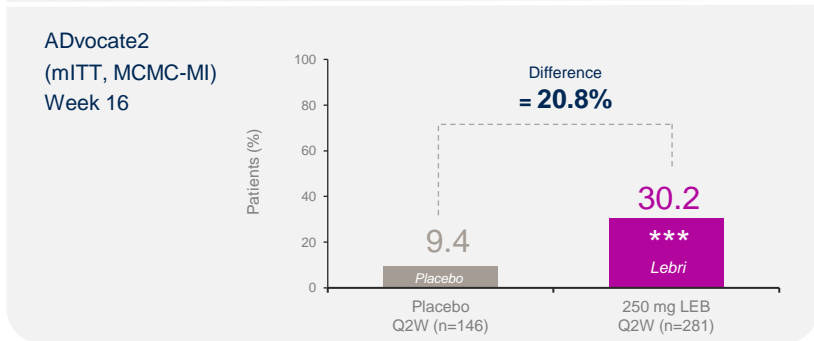
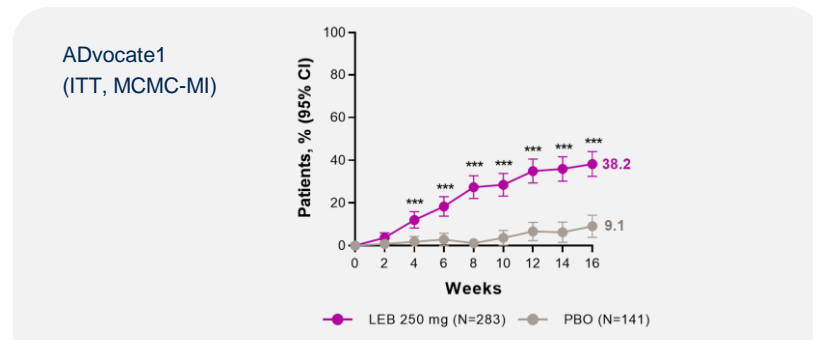
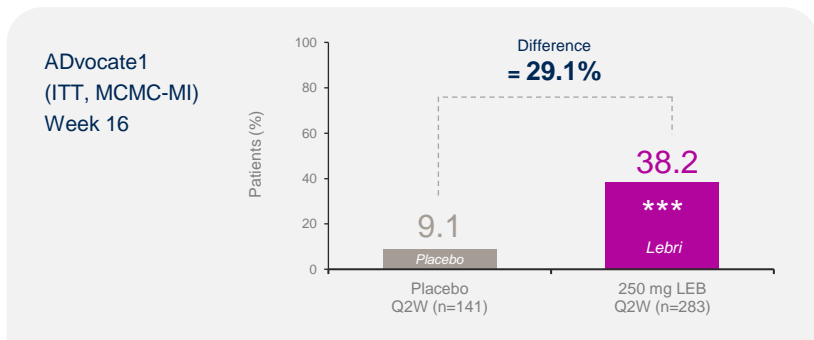
ADvocate2
(mITT, MCMC-MI)



* p<0.05; ** p<0.01; *** p<0.001 vs. PBO based on the Cochran-Mantel-Haenszel test stratified by geographic region (US vs. Europe vs. rest of world), age (adolescents 12 to <18 years old vs. adults ≥18 years old), and disease severity (baseline IGA score of 3 vs. 4). Missing data as a result of rescue medication or treatment discontinuation due to lack of efficacy were imputed with baseline values; missing data due to other reasons were imputed with MCMC-MI within treatment arms. CI=confidence interval; IGA=Investigator's Global Assessment; ITT=Intent-to-Treat; LEB=lebrikizumab; MCMC-MI=Markov Chain Monte Carlo multiple imputation; mITT=modified ITT; PBO=placebo; Q2W=every 2 weeks.

Key secondary efficacy endpoints

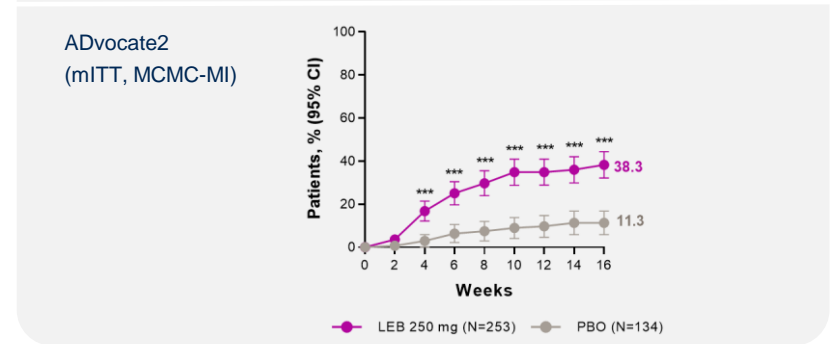
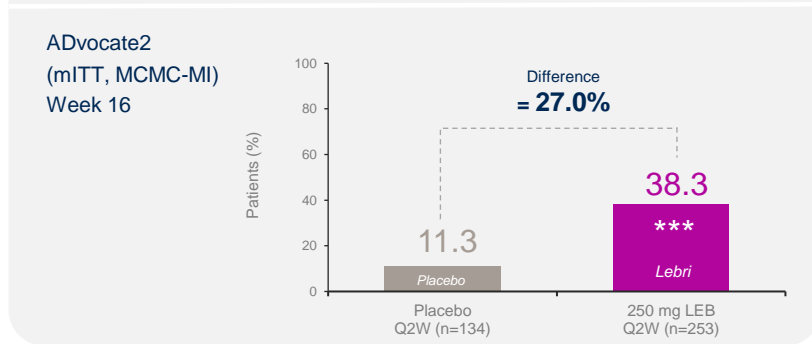
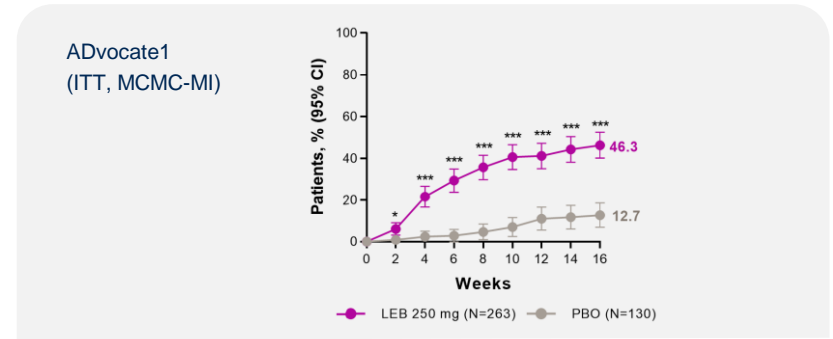
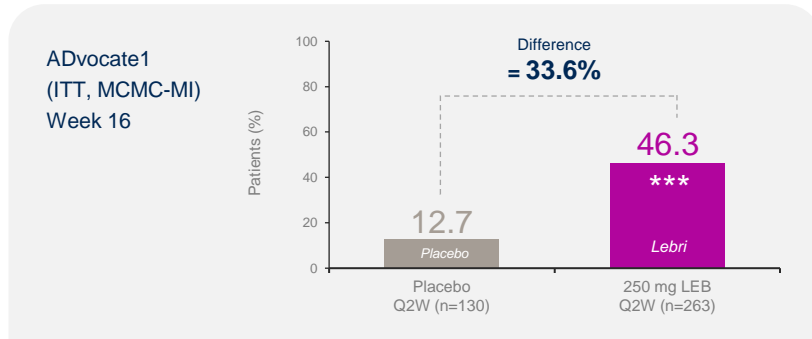
EASI-90 response rate



* p<0.05; ** p<0.01; *** p<0.001 vs. PBO based on the Cochran-Mantel-Haenszel test stratified by geographic region, age group, and baseline IGA score. Missing data as a result of rescue medication or treatment discontinuation due to lack of efficacy were imputed with baseline values; missing data due to other reasons were imputed with MCMC-MI within treatment arms. CI=confidence interval; EASI=Eczema Area and Severity Index; EASI-90=90% reduction from baseline in EASI score; IGA=Investigator's Global Assessment; ITT=Intent-to-Treat; LEB=lebrikizumab; MCMC-MI=Markov Chain Monte Carlo multiple imputation; mITT=modified ITT; NRS=numeric rating scale; PBO=placebo.

Key secondary efficacy endpoints

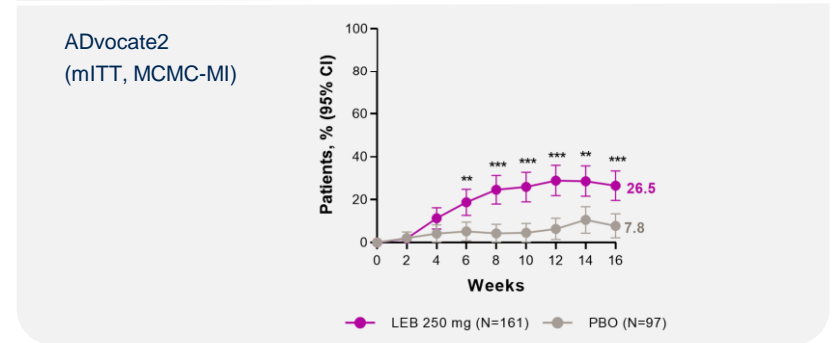
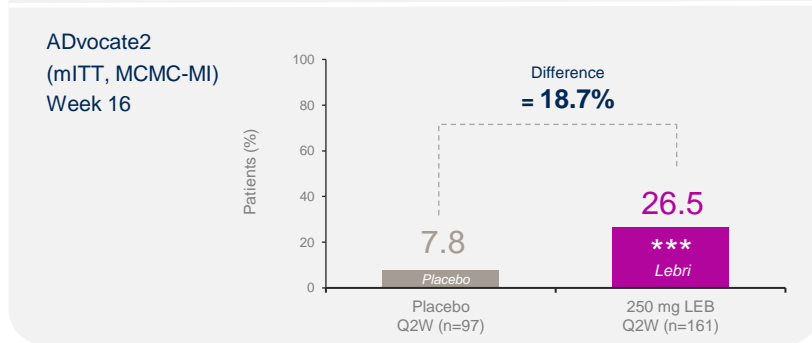
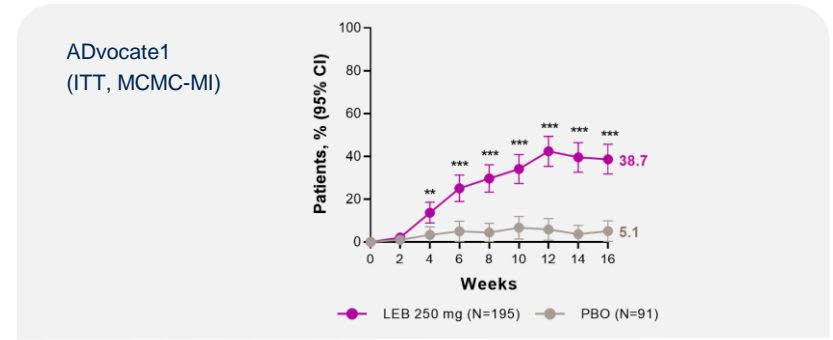
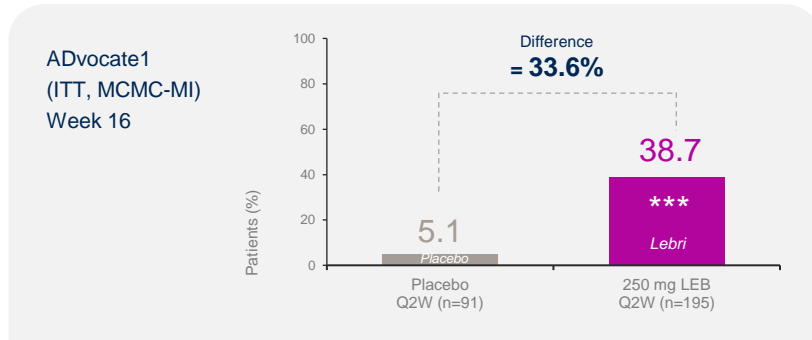
Pruritus NRS ≥ 4 -point improvement^a from baseline



* p<0.05; ** p<0.01; *** p<0.001 vs. PBO based on the Cochran-Mantel-Haenszel test stratified by geographic region, age group, and baseline IGA score. Missing data as a result of rescue medication or treatment discontinuation due to lack of efficacy were imputed with baseline values; missing data due to other reasons were imputed with MCMC-MI within treatment arms. ^a For patients with pruritus NRS ≥ 4 at baseline. CI=confidence interval; DLQI=Dermatology Life Quality Index; EASI=Eczema Area and Severity Index; EASI-90=90% reduction from baseline in EASI score; IGA=Investigator's Global Assessment; ITT=Intent-to-Treat; LEB=lebrikizumab; MCMC-MI=Markov Chain Monte Carlo multiple imputation; mITT=modified ITT; NRS=numeric rating scale; PBO=placebo.

Key secondary efficacy endpoints

Sleep loss NRS ≥ 2 -point improvement^a from baseline

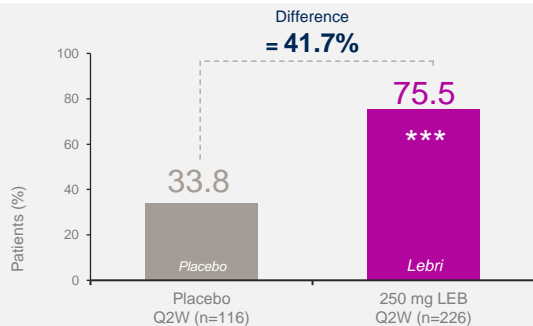


* p<0.05; ** p<0.01; *** p<0.001 vs. PBO based on the Cochran-Mantel-Haenszel test stratified by geographic region, age group, and baseline IGA score. Missing data as a result of rescue medication or treatment discontinuation due to lack of efficacy were imputed with baseline values; missing data due to other reasons were imputed with MCMC-MI within treatment arms. ^a For patients with Sleep-Loss Scale score ≥ 2 at baseline. CI=confidence interval; DLQI=Dermatology Life Quality Index; EASI=Eczema Area and Severity Index; EASI-90=90% reduction from baseline in EASI score; IGA=Investigator's Global Assessment; ITT=Intent-to-Treat; LEB=lebrikizumab; MCMC-MI=Markov Chain Monte Carlo multiple imputation; mITT=modified ITT; NRS=numeric rating scale; PBO=placebo.

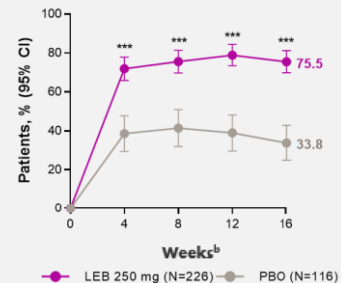
Key secondary efficacy endpoints

Quality of life: DLQI ≥ 4 -point improvement^a from baseline

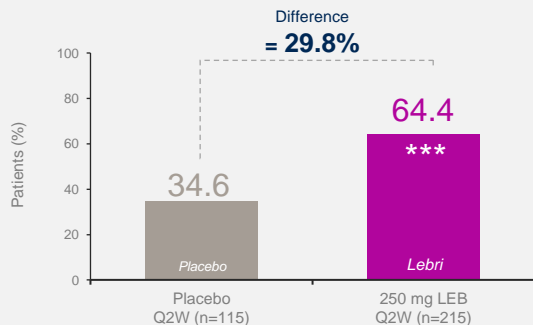
ADvocate1
(ITT, MCMC-MI)
Week 16



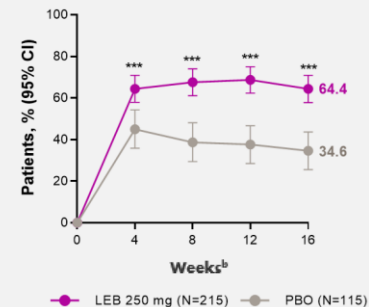
ADvocate1
(ITT, MCMC-MI)



ADvocate2
(mITT, MCMC-MI)
Week 16



ADvocate2
(mITT, MCMC-MI)



* p<0.05; ** p<0.01; *** p<0.001 vs. PBO based on the Cochran-Mantel-Haenszel test stratified by geographic region, age group, and baseline IGA score. Missing data as a result of rescue medication or treatment discontinuation due to lack of efficacy were imputed with baseline values; missing data due to other reasons were imputed with MCMC-MI within treatment arms. ^a For patients with DLQI ≥ 4 at baseline; ^b DLQI measured at baseline and Weeks 4, 8, 12, and 16. CI=confidence interval; DLQI=Dermatology Life Quality Index; EASI=Eczema Area and Severity Index; EASI-90=90% reduction from baseline in EASI score; IGA=Investigator's Global Assessment; ITT=Intent-to-Treat; LEB=lebrikizumab; MCMC-MI=Markov Chain Monte Carlo multiple imputation; mITT=modified ITT; NRS=numeric rating scale; PBO=placebo.

Lebrikizumab was well tolerated

Overall incidence of adverse events comparable to placebo

	ADvocate1 (Safety Population)		ADvocate2 (Modified Safety Population ^c)	
	Placebo Q2W (N=141)	LEB 250 mg Q2W (N=282)	Placebo Q2W (N=145)	LEB 250 mg Q2W (N=281)
Any TEAE	72 (51.5)	128 (45.4)	96 (66.2)	149 (53.0)
Mild	34 (24.1)	78 (27.7)	40 (27.6)	73 (26.0)
Moderate	31 (22.0)	44 (15.6)	49 (33.8)	69 (24.6)
Severe	7 (5.0)	6 (2.1)	7 (4.8)	7 (2.5)

Most common TEAEs (≥5% in either LEB group)

Conjunctivitis^a	4 (2.8)	21 (7.4)	3 (2.1)	22 (7.8)
Exacerbation of AD	28 (19.9)	15 (5.3)	37 (25.5)	28 (10.0)
Nasopharyngitis	3 (2.1)	11 (3.9)	3 (2.1)	14 (5.0)
Headache	2 (1.4)	9 (3.2)	6 (4.1)	14 (5.0)
Serious AE ^b	1 (0.7)	6 (2.1)	4 (2.8)	2 (0.7)
Death	0	0	1 (0.7)	0
AEs leading to treatment discontinuation ^b	1 (0.7)	3 (1.1)	4 (2.8)	8 (2.8)
Injection site reactions	3 (2.1)	3 (1.1)	1 (0.7)	7 (2.5)
Herpes infections	6 (4.3)	9 (3.2)	6 (4.1)	8 (2.8)

Data are n (%). ^a Conjunctivitis single preferred term; ^b Deaths are also included as serious AEs and AEs leading to treatment discontinuation. ^c Rescue medication or treatment discontinuation due to lack of efficacy were imputed with baseline values; otherwise, Markov Chain Monte Carlo multiple imputation (MCMC-MI) within treatment arms was applied.
AD=atopic dermatitis; AE=adverse event; LEB=lebrikizumab; PBO=placebo; Q2W=every 2 weeks; TEAE=treatment-emergent adverse event.

Lebrikizumab 16 week phase 3 data

Key Takeaways

Lebrikizumab phase 3, week 16 data

These data from two pivotal phase 3 trials suggest that **lebrikizumab 250 mg Q2W is efficacious for patients with moderate-to-severe AD.**

Lebrikizumab 250 mg **demonstrated rapid efficacy in primary and key secondary endpoints.** Statistical significance was achieved in key endpoints within 4 weeks.

Most TEAEs **were mild or moderate in severity**, nonserious, and there were few injection site reactions.

The lebrikizumab phase 3 data reinforces the role of IL13 as the key pathogenic driver in AD.

Q2W=every 2 weeks, AD=atopic dermatitis, TEAE=treatment-emergent adverse event.

Lebrikizumab 16 week phase 3 data

Closing Remarks



AD an underserved and growing market

Almirall to leverage strong commercial footprint in Europe



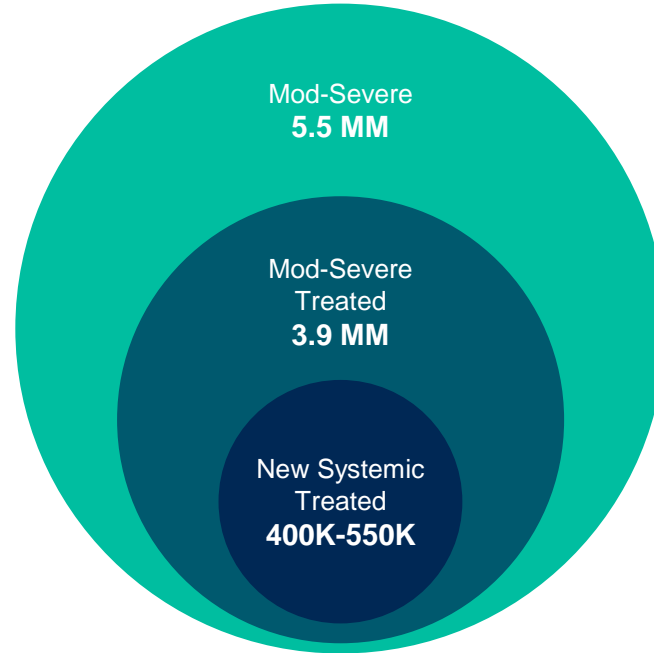
Number of atopic dermatitis patients treated with biologics is expected to be at least comparable with psoriasis by 2026.*



A meaningful share of Moderate-Severe patients are expected to be treated with new systemics.*



Peak sales of €450 MM expected in Europe.



18 MM

atopic dermatitis patients in EU by 2026

* Psoriasis – Disease Landscape & Forecast, DRG Nov 2017, Atopic Dermatitis/Atopic Eczema – Disease Landscape & Forecast, DRG Dec 2017.

Conclusions

Compelling profile



Fast onset of action with Lebrikizumab rapidly improved skin and itch symptoms within 4 weeks.

Lebrikizumab led to significant improvements with >50% of people treated achieved at least 75% improvement in overall disease severity (EASI-75) at week 16.



On track for a 2023 potential approval in the EU, as we continue to work with our partner Eli Lilly on our commitment to improve lives of patients with atopic dermatitis.

Phase 3 study confirms Lebrikizumab may potentially offer a compelling combination of efficacy and safety, reinforcing our belief that Lebrikizumab represents the next generation of biologics.

Expect completion of ADVocate 1 & 2 studies in H1 2022. Global regulatory submissions to occur in late 2022 based on data from the phase 3 clinical trial program.

* Psoriasis – Disease Landscape & Forecast, DRG Nov 2017, Atopic Dermatitis/Atopic Eczema – Disease Landscape & Forecast, DRG Dec 2017. EASI=Eczema Area and Severity Index.

Appendices

ADvocate 1 & 2

	ADvocate1 (ITT)		ADvocate2 (mITT)	
	Placebo Q2W (N=141)	LEB 250 mg Q2W (N=283)	Placebo Q2W (N=146)	LEB 250 mg Q2W (N=281)
Age, years	34.2 (16.4)	36.1 (17.8)	35.3 (17.2)	36.6 (16.8)
Adolescent (12 to <18 years old), n (%)	18 (12.8)	37 (13.1)	17 (11.6)	30 (10.7)
Adult (≥18 years old), n (%)	123 (87.2)	246 (86.9)	129 (88.4)	251 (89.3)
Female, n (%)	73 (51.8)	141 (49.8)	75 (51.4)	136 (48.4)
Region, n (%)				
US	62 (44.0)	128 (45.2)	60 (41.1)	107 (38.1)
Europe	46 (32.6)	92 (32.5)	38 (26.0)	76 (27.0)
Rest of world	33 (23.4)	63 (22.3)	48 (32.9)	98 (34.9)
Race, n (%)				
White	93 (66.0)	196 (69.3)	85 (58.2)	168 (59.8)
Asian	31 (22.0)	39 (13.8)	44 (30.1)	78 (27.8)
Black/African American	16 (11.3)	33 (11.7)	10 (6.8)	25 (8.9)
BMI, kg/m²	27.8 (7.2)	26.5 (5.8)	26.2 (6.2)	26.6 (6.6)
Prior systemic treatment, n (%)	85 (60.3)	144 (50.9)	81 (55.5)	156 (55.5)

Baseline
demographics &
characteristics

Data are from the 16-week primary outcome database lock with data cut-off dates of 21 June 2021 (ADvocate1) and 12 July 2021 (ADvocate2). Data are mean (standard deviation), unless stated otherwise. BMI=body mass index; ITT=Intent-to-Treat; LEB=lebrikizumab; mITT=modified ITT; PBO=placebo; Q2W=every 2 weeks.

Lebrikizumab 16 week phase 3 data

ADvocate 1 & 2

	ADvocate1 (ITT)		ADvocate2 (mITT)	
	Placebo Q2W (N=141)	LEB 250 mg Q2W (N=283)	Placebo Q2W (N=146)	LEB 250 mg Q2W (N=281)
Disease duration since AD diagnosis, years	23.7 (15.4)	22.0 (14.8)	20.1 (14.4)	20.8 (15.2)
IGA, n (%)				
3 (moderate)	83 (58.9)	170 (60.1)	95 (65.1)	175 (62.3)
4 (severe)	58 (41.1)	113 (39.9)	51 (34.9)	106 (37.7)
EASI	31.0 (12.9)	28.8 (11.3)	29.6 (10.8)	29.7 (12.0)
BSA % involvement	47.8 (23.9)	45.3 (22.5)	46.0 (21.1)	46.1 (22.6)
SCORAD	67.1 (12.3)	65.6 (11.7)	66.2 (10.0)	66.5 (12.0)
Pruritus NRS	7.3 (1.7)	7.2 (1.9)	7.2 (1.9)	7.1 (1.9)
Sleep-Loss Scale score	2.3 (1.0)	2.3 (1.0)	2.2 (0.9)	2.2 (0.9)
DLQI^a	15.7 (7.2)^b	15.3 (7.4)^c	15.9 (7.6)^d	15.4 (7.0)^e

Baseline disease characteristics

Data are mean (standard deviation), unless stated otherwise. a DLQI was completed only for patients ≥16 years of age at baseline; patients <16 years of age used the Children's DLQI. Patients who answered DLQI at baseline: b n=121; c n=239; d n=118; e n=218. AD=atopic dermatitis; BSA=body surface area; DLQI=Dermatology Life Quality Index; EASI=Eczema Area and Severity Index; IGA=Investigator's Global Assessment; ITT=Intent-to-Treat; LEB=lebrikizumab; mITT=modified ITT; NRS=numeric rating scale; PBO=placebo; Q2W=every 2 weeks; SCORAD=SCORing AD.

Lebrikizumab 16 week phase 3 data

ADvocate 1 & 2

	ADvocate1 (ITT)		ADvocate2 (mITT)	
	Placebo Q2W (N=141)	LEB 250 mg Q2W (N=283)	Placebo Q2W (N=146)	LEB 250 mg Q2W (N=281)
Any rescue medication^a	47 (33.3)	30 (10.6)	58 (39.7)	56 (19.9)
Topical rescue medication	44 (31.2)	27 (9.5)	54 (37.0)	52 (18.5)
Low-moderate potency TCS	38 (27.0)	21 (7.4)	24 (16.4)	28 (10.0)
High potency TCS	15 (10.6)	6 (2.1)	36 (24.7)	25 (8.9)
Topical calcineurin inhibitor	9 (6.4)	3 (1.1)	6 (4.1)	11 (3.9)
Systemic rescue medication	11 (7.8)	6 (2.1)	9 (6.2)	8 (2.8)

Use of rescue medication through week 16

Data are n (%). a Patients who used any rescue therapy during the Induction Period were considered non-responders
ITT=Intent-to-Treat; LEB=lebrikizumab; mITT=modified ITT; PBO=placebo; Q2W=every 2 weeks; TCS=topical corticosteroids.

Lebrikizumab 16 week phase 3 data



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