

Rademikibart monotherapy in adult and adolescent patients with moderate-to-severe atopic dermatitis (AD): A 1-year, phase III, randomized, double-blinded, placebo-controlled trial (RADIANT-AD)

Prof. Cheng Zhou

on behalf of the RADIANT-AD study team

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Disclosures

- Aik Han Goh, Lihong Zhuang and Xiaoyu Zhang are employees of Jiangsu Simcere Pharmaceutical and hold stock share.
- The rest authors have no relationships to disclose.

Still high unmet medical needs in atopic dermatitis



~129 million in 2021¹
Increasing prevalence worldwide



~30% Children and adolescents²
High requirement for both efficacy and safety



~50% moderate-severe^{2,4}
Need systemic treatment



~52% increase in annual per-person cost³
Might be more in the future

With current AD biologic choices:

- **Still low response rate of current anti-IL-4 mAb during induction phase**

EASI-75 responders 34.4% at W16⁴

IGA 0/1 responders 27.6% at W16⁴

- **Unsatisfied deep clearance**

EASI-90 responders 25.4% at W16⁴

Physicians and AD patients need more options

Still high unmet needs for new therapy that induces deep clearance and sustains long-term efficacy safely.

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2. National Eczema Association. Atopic dermatitis. Accessed October 29, 2024. <https://nationaleczema.org/eczema/types-of-eczema/atopic-dermatitis/>

3. Clara Weil, et al (2022), Adv Ther 39:2502–2514, doi.org/10.1007/s12325-022-02120-6;

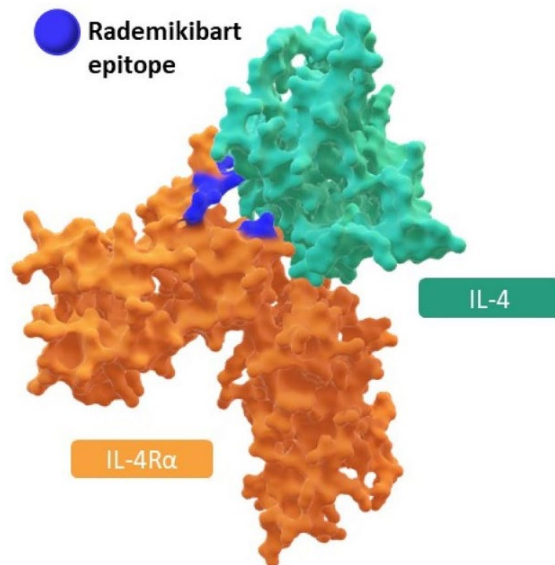
4. Diamant Thaçi et al (2019), Journal of Dermatological Science 94: 266–275, doi.org/10.1016/j.jdermsci.2019.02.002

Rademikibart: Next-generation biologics with higher affinity for IL-4R α

Rademikibart is a fully human monoclonal antibody targeting interleukin-4 receptor alpha (IL-4R α), thus blocking IL-4 and IL-13 pathways.

Distinct epitope¹

Rademikibart binds human IL-4R α via a **distinct epitope** from Dupilumab



Higher affinity¹

Rademikibart achieved equivalent effects with **lower concentration** than dupilumab

	Rademikibart	Dupilumab
K _D (pM)	20.7	45.8
STAT6 signaling	7.0	9.9
IC ₅₀ (ng/ml) TF-1 cell proliferation	8.0	10.8
TARC secretion	59.2	65.2

Multiple indications

Looking forward to **more data** of Rademikibart this year!



RADIANT-AD

Ph3 study completed



RADIANT-Asthma

Ph3 study on-going



Asthma exacerbation

Ph2 study on-going

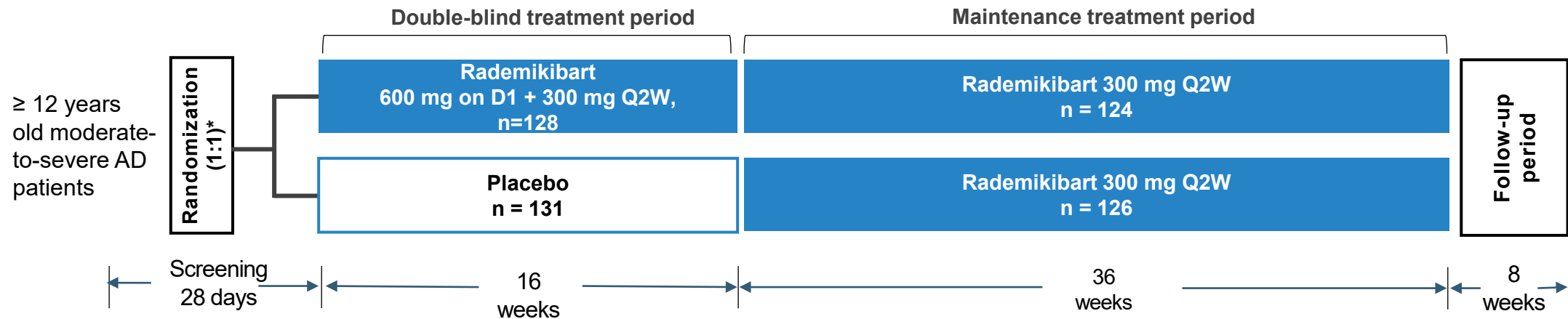


COPD exacerbation

Ph2 study on-going

RADIANT-AD Study Design

- **Design:** a randomized, double-blind, placebo-controlled, phase 3 study at 57 study centers (NCT05017480)
- **Eligible patients:** ≥ 12 years old moderate-to-severe atopic dermatitis (AD) patients with EASI ≥ 16 , IGA score ≥ 3 (5-point scale [0-4]), $\geq 10\%$ BSA involvement, and weekly average of daily PP-NRS score ≥ 4
- ★ **Co-Primary endpoints:**
 - ① Proportion of subjects achieving IGA score of 0/1 with ≥ 2 -point reduction at Week 16
 - ② Proportion of subjects achieving $\geq 75\%$ improvement from baseline in EASI (EASI-75) at Week 16
- **Actual enrollment:** 259 patients (204 adults, 55 adolescents)



*Randomization stratified by: (1) baseline disease severity (IGA=3, IGA=4), (2) age (adult, adolescent)

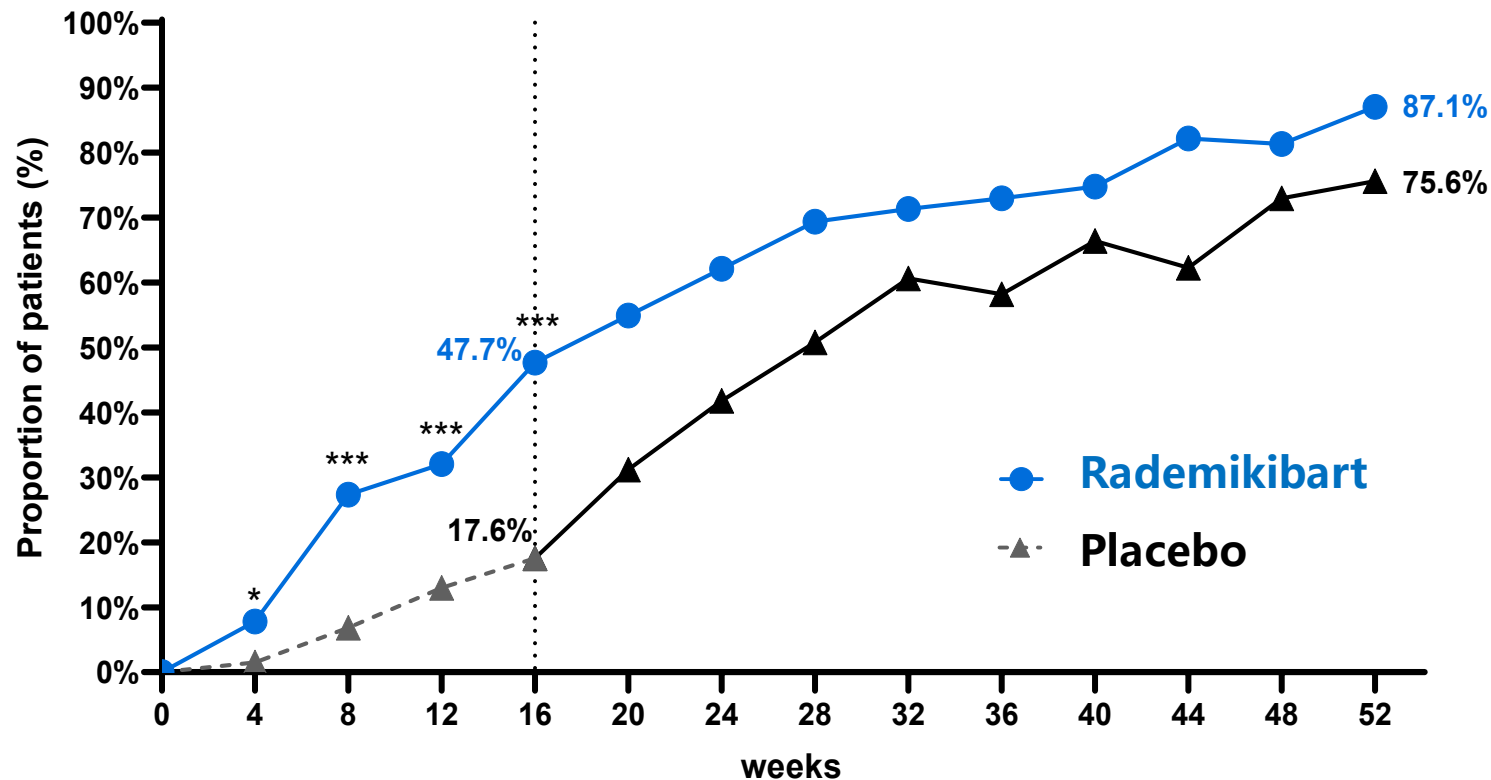
Baseline characteristics were generally balanced between Rademikibart and placebo groups

Baseline Disease Characteristics	Rademikibart (N = 128)	Placebo (N = 131)	Overall (N = 259)
Age (y), mean (SD)	33.7 (17.5)	32.7 (16.4)	33.2 (16.9)
Age (y), n (%)			
12 - <18	27 (21.1%)	28 (21.4%)	55 (21.2%)
≥18	101 (78.9%)	103 (78.6%)	204 (78.8%)
Male sex, n (%)	83 (64.8)	85 (64.9)	168 (64.9)
BMI (kg/m ²), mean (SD)	24.1 (4.4)	23.9 (3.9)	24.0 (4.2)
Weight (kg), mean (SD)	68.4 (14.7)	68.1 (15.5)	68.3 (15.1)
Disease duration (y), mean (SD)	9.0 (6.8)	8.9 (6.9)	8.9 (6.8)
Affected BSA, mean (SD)	34.3% (17.7%)	32.9% (16.9%)	33.6% (17.3%)
IGA = 3, n (%)	76 (59.4%)	77 (58.8%)	153 (59.1%)
IGA = 4, n (%)	52 (40.6%)	54 (41.2%)	106 (40.9%)
EASI, mean (SD)	24.1 (9.2)	23.4 (8.8)	23.7 (9.0)
PP-NRS, mean (SD)	7.1 (1.4)	7.3 (1.4)	7.2 (1.4)

AD : atopic dermatitis; BMI: Body Mass Index; BSA: body surface area; EASI: eczema area and severity index; IGA: investigator global assessment; PP-NRS: Pruritus numeric rating scale

IGA 0/1 with 2-point reduction was significantly improved by Rademikibart at W16 and continued to rise up to W52

IGA score of 0/1 with 2-point reduction

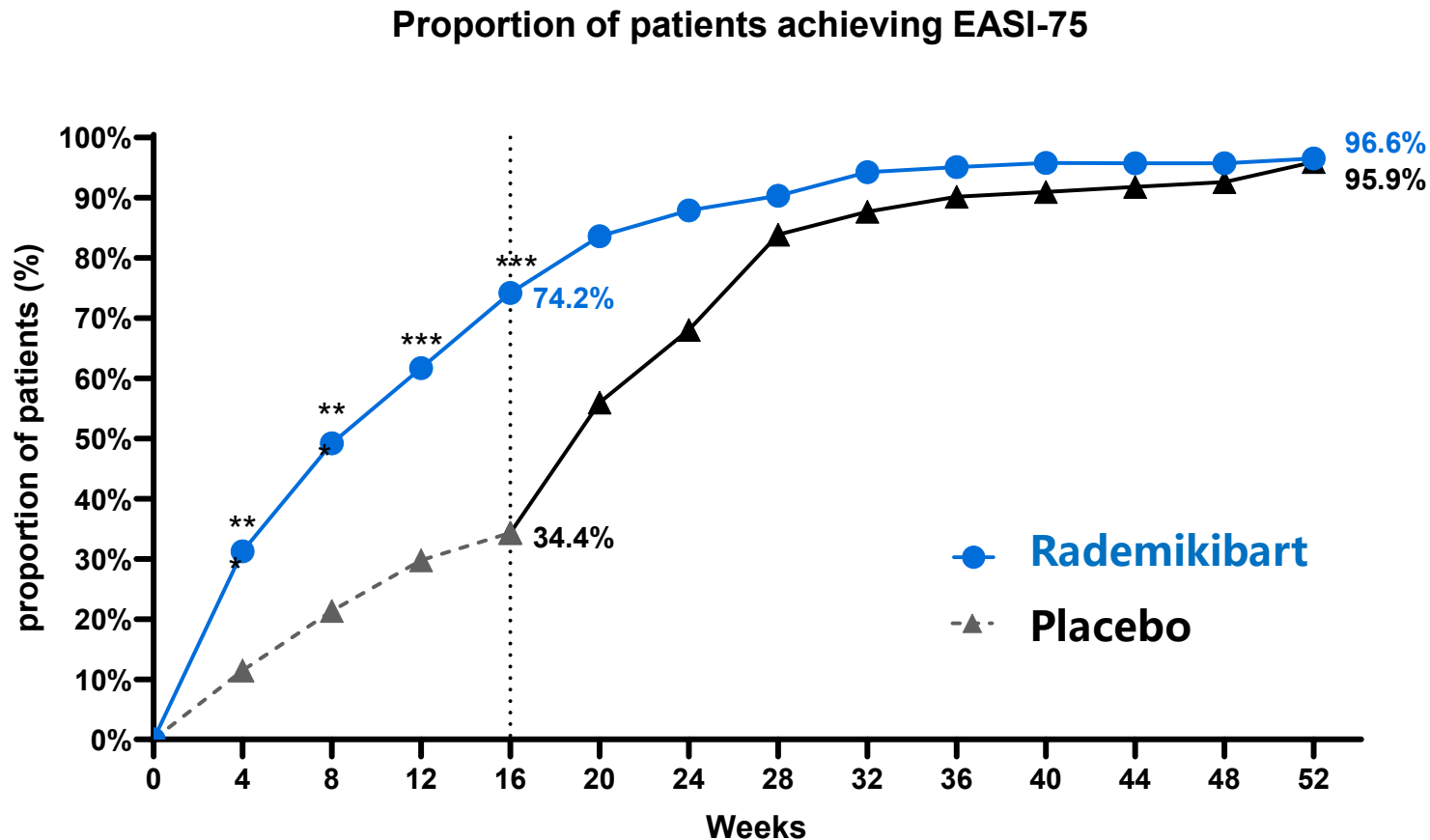


- Proportion of patients achieving IGA 0/1 with 2-point reduction at W16 was statistically significantly higher in Rademikibart group compared to placebo IGA0/1 response continued to rise until W52, reaching **87.1%**.
- After switching to Rademikibart treatment, placebo group showed rapid response, reaching 75.6% at W52.

***, **, * represent statistically significant at the one-sided α level of 0.0005, 0.005, and 0.025, respectively.

Note: The summaries for weeks 16 and earlier are based on the Full Analysis Set (FAS), with missing data handled using non-response imputation; summaries for weeks after week 16 are based on observed values, without any imputation.

EASI-75 response was significantly improved by Rademikibart at W16 and sustained through W52



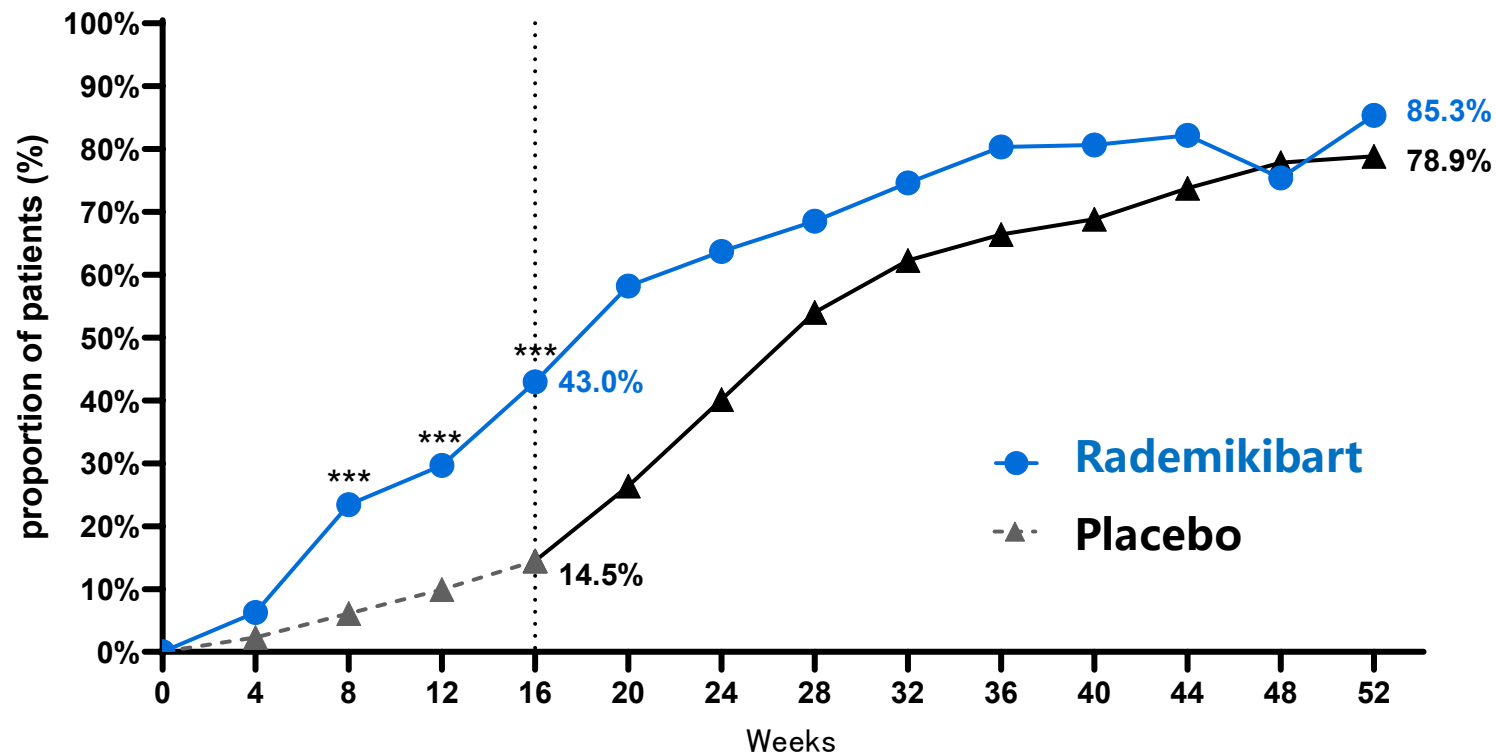
- EASI-75 response at W16 was statistically significantly higher in the Rademikibart group compared to placebo EASI-75 response demonstrated continued improvement through W52, reaching **96.6%**.
- After switching to Rademikibart treatment, placebo group showed rapid response, reaching 95.9% at W52.

***, **, * represent statistically significant at the one-sided α level of 0.0005, 0.005, and 0.025, respectively.

Note: The summaries for weeks 16 and earlier are based on the Full Analysis Set (FAS), with missing data handled using non-response imputation; summaries for weeks after week 16 are based on observed values, without any imputation.

Rademikibart induced and maintained deep clearance of skin lesions compared to placebo

Proportion of patients achieving EASI-90



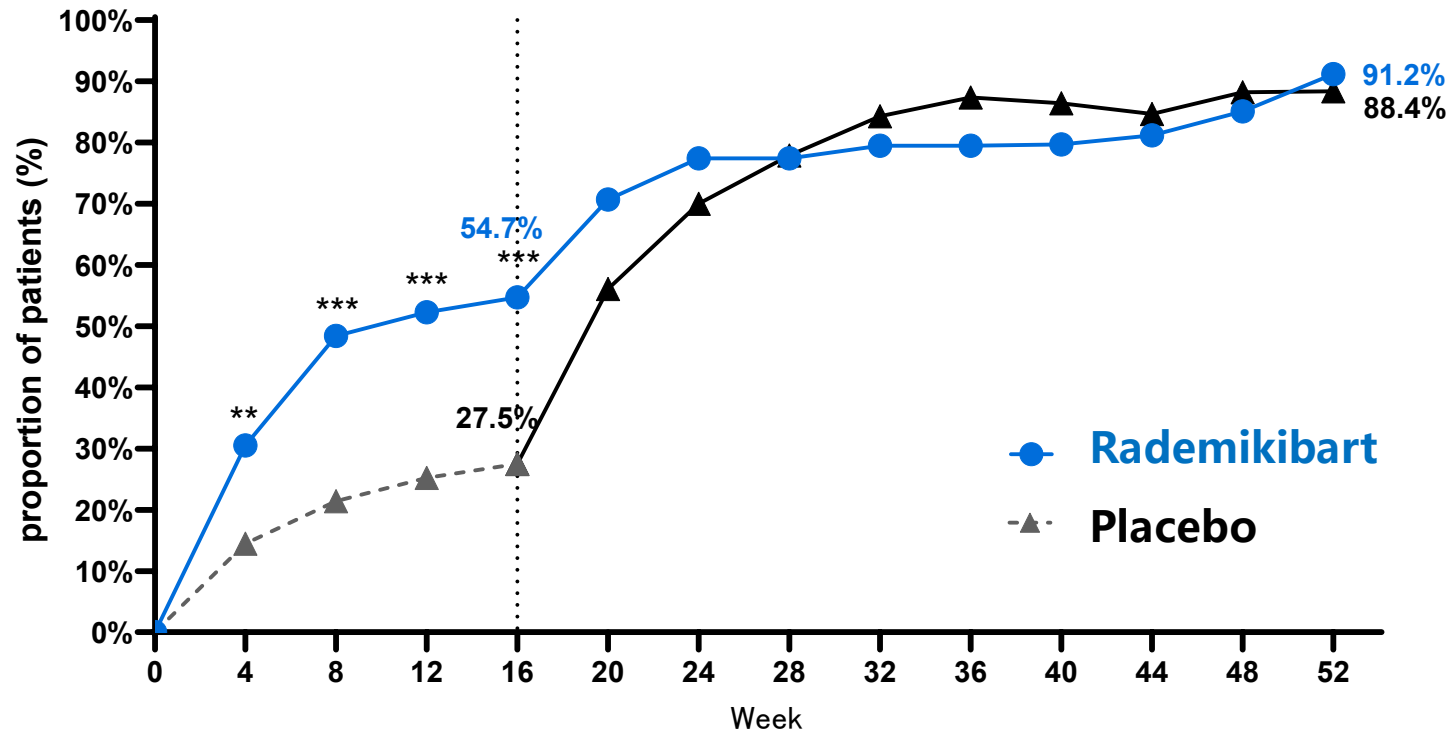
- EASI-90 response at W16 was statistically significantly higher in the Rademikibart group compared to the placebo EASI-90 response and continued to improve through W52, reaching 85.3%.
- After switching to Rademikibart treatment, placebo group showed rapid response, reaching 78.9% at W52.

***, **, * represent statistically significant at the one-sided α level of 0.0005, 0.005, and 0.025, respectively.

Note: The summaries for weeks 16 and earlier are based on the Full Analysis Set (FAS), with missing data handled using non-response imputation; summaries for weeks after week 16 are based on observed values, without any imputation.

Rapid and sustained antipruritic effects of Rademikibart

≥3-point improvement in weekly average of PP-NRS score



- Proportion of patients achieving ≥3-point improvement at W16 in weekly average of PP-NRS score was statistically significantly higher in Rademikibart group compared to placebo PP-NRS≥3 response and continued to improve through to W52, reaching 91.2%.
- After switching to Rademikibart treatment, placebo group showed rapid response, reaching 88.4% at W52.

***, **, * represent statistically significant at the one-sided α level of 0.0005, 0.005, and 0.025, respectively.

Note: The summaries for weeks 16 and earlier are based on the Full Analysis Set (FAS), with missing data handled using non-response imputation; summaries for weeks after week 16 are based on observed values, without any imputation.

TEAE and TRAE occurrence rates following Rademikibart treatment were comparable to placebo (W0-W16)

TEAE summary W0-W16

	Rademikibart (N = 128) n (%)	Placebo (N = 131) n (%)
TEAE	78 (60.9%)	85 (64.9%)
Grade 3 TEAE	3 (2.3%)	0
Grade 4 TEAE	0	0
Grade 5 TEAE	0	0
TRAE	24 (18.8%)	35 (26.7%)
SAE*	3 (2.3%)	0
SAE related to study treatment	0	0
TEAE Leading to treatment permanent discontinuation**	1 (0.8%)	0
Injection site reaction	2 (1.6%)	0
Conjunctivitis	5 (3.9%)	4 (3.1%)

*3 SAEs were meniscus injury (D94), pneumonitis (D61, with related medical history at Screening), pulmonary mass/lung adenocarcinoma (D7).

**TEAE leading to treatment permanent discontinuation was pulmonary mass/lung adenocarcinoma (D7) and not related to rademikibart

≥ 3% TEAEs in Rademikibart group W0-W16

TEAE PT term	Rademikibart (N = 128) n (%)	Placebo (N = 131) n (%)
Upper respiratory tract infection	23 (18%)	18 (13.7%)
TG increased	6 (4.7%)	3 (2.3%)
Conjunctivitis	5 (3.9%)	4 (3.1%)
Hyperuricemia	5 (3.9%)	2 (1.5%)
Acne	3 (3.1%)	1 (0.8%)
ALT increased	3 (3.1%)	8 (6.1%)
CK increased	3 (3.1%)	4 (3.1%)

TG: triglyceride; ALT: alanine aminotransferase; CK: creatine phosphokinase; PT: Preferred Term; TEAE: Treatment Emergent Adverse Event; TREA: Treatment Related Adverse Event; SAE: Serious Adverse Event; W: Week.

Rademikibart has a safety profile for long-term treatment (W0-W52) consistent with other anti-IL-4 mAb

TEAE summary W0-W52

	Rademikibart (N = 128) W0-W52 n (%)	Placebo- Rademikibart (N = 106) W16-W52 n (%)
TEAE	106 (82.8%)	87 (69.0%)
Grade 3 TEAE	8 (6.3%)	7 (5.6%)
Grade 4 TEAE	0	0
Grade 5 TEAE	0	0
TRAE	40 (31.3%)	30 (23.8%)
SAE	7 (5.5%)	6(4.8%)
SAE related to study treatment*	1 (0.8%)	1 (0.8%)
TEAE Leading to treatment permanent discontinuation**	1 (0.8%)	1 (0.8%)
Injection site reaction	2 (1.6%)	0
Conjunctivitis	8 (6.3%)	7 (5.6%)

*SAE related to study treatment was vasovagal syncope (D154) and vestibular neuronitis (D229).

** pulmonary mass/lung adenocarcinoma (D7) and parotid gland enlargement/lymphadenopathy (D206, with related medical history)

≥ 3% TEAEs in Rademikibart group W0-W52

TEAE term	Rademikibart (N = 128) n (%)
Upper respiratory tract infection	35 (27.3%)
CK increased	10 (7.8%)
Conjunctivitis	7 (5.5%)
TG increased	7 (5.5%)
Acne	6 (4.7%)
ALT increased	6 (4.7%)
Blood bilirubin increased	6 (4.7%)
Hyperuricemia	6 (4.7%)
LDL increased	5 (3.9%)
Weight increased	5 (3.9%)
Cough	4 (3.1%)
Diarrhea	4 (3.1%)
Gastroenteritis	4 (3.1%)
GGT increased	4 (3.1%)
Urine protein present	4 (3.1%)

CK: creatine phosphokinase; TG: triglyceride; ALT: alanine aminotransferase; LDL: low-density lipoprotein; GGT: gamma-glutamyltransferase; TEAE: Treatment Emergent Adverse Event; TRAE: Treatment Related Adverse Event; SAE: Serious Adverse Event; W: Week.

Conclusions

Rademikibart treatment in both adult and adolescent patients with moderate-to-severe atopic dermatitis demonstrated:

- **Rapid and sustained efficacy through 52 weeks**, with minimal plateau and near-maximal response achieved by ~90% of patients
- **Greater long-term benefit with early initiation**, with higher Week-52 IGA response versus delayed switch from placebo at Week 16
- **Favorable safety profile**, comparable to placebo and well tolerated with long-term use
- **Low rates of conjunctivitis**, consistent with prior studies and comparable to placebo

	W16 response rate			W52 response rate	
	Rademikibart	Placebo	Statistical Significance	Rademikibart	Placebo-Rademikibart
IGA 0/1	47.4%	17.6%	p<0.001	87.1%	75.6%
EASI-75	74.2%	34.4%	p<0.0001	96.6%	95.9%
EASI-90	43.0%	14.5%	p<0.0001	85.3%	78.9%
PP-NRS≥3	54.7%	27.5%	p<0.0001	91.2%	88.4%

Additional patient-reported outcomes and adolescent-specific analyses from the RADIANT-AD study will be reported separately at a later date

Acknowledgement

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