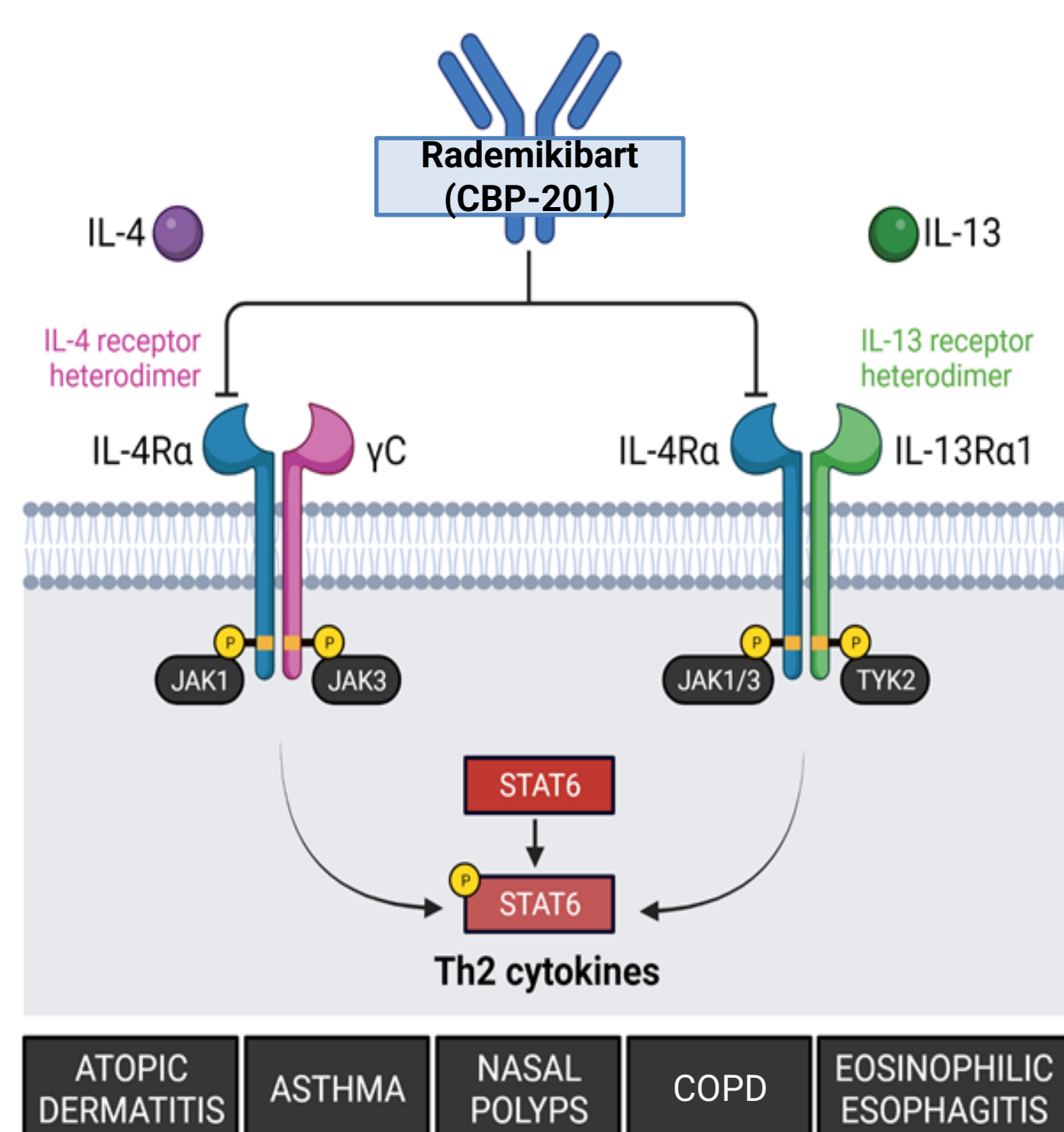


# Continued Improvement of Investigator and Patient Reported Outcomes into the 52-Week Maintenance Period were Observed with Rademikibart in Patients with Moderate-to-Severe Atopic Dermatitis (SEASIDE CHINA)

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Abstract 6518

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- Rademikibart (formerly CBP-201) is a next-generation, high-affinity mAb, inhibiting the actions of IL-4 and IL-13.
- In preclinical studies, rademikibart bound with higher affinity to distinct IL-4Rα epitopes, and potentially downregulated intracellular signaling and cytokine gene expression, compared with dupilumab.<sup>1,2</sup>
- In international and China-specific clinical trials, rademikibart achieved large reductions in AD signs and symptoms.<sup>3-11</sup>
- In Stage 1 (16 weeks), rademikibart achieved all primary and secondary efficacy endpoints in SEASIDE CHINA (CN002; NCT05017480), and was well tolerated, by patients with moderate-to-severe AD.<sup>7-11</sup>

## Objective

We report continuous efficacy improvements across 52 weeks of rademikibart therapy, focusing on Stage 2 maintenance data (36 weeks), in the SEASIDE CHINA pivotal trial.

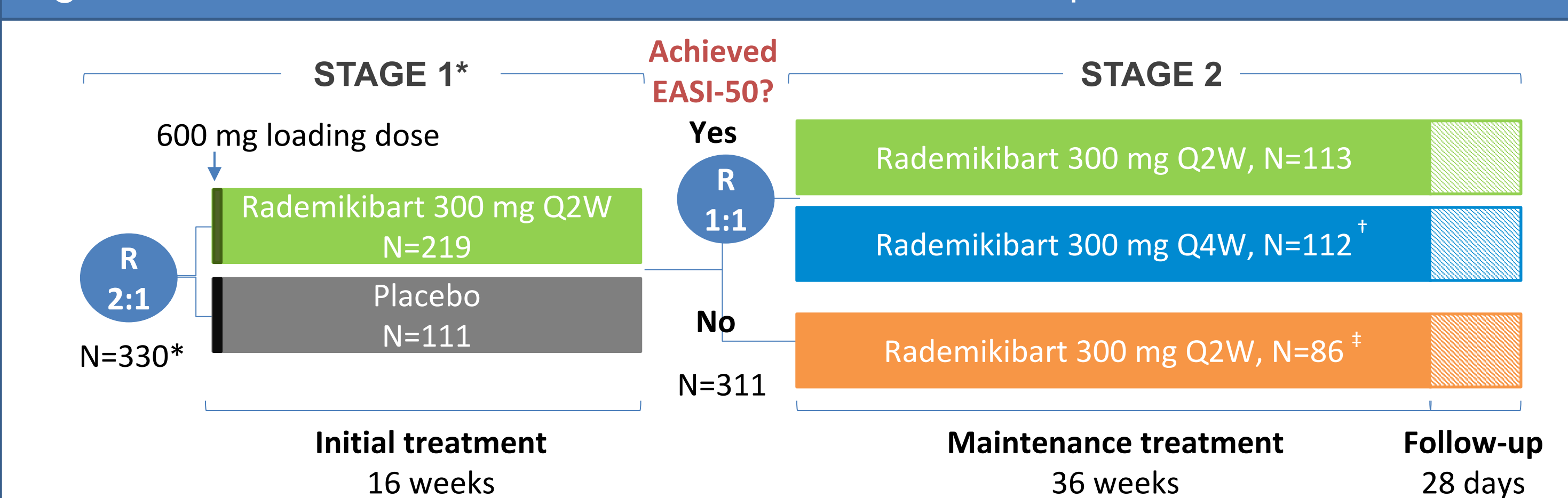
## Methodology

### Study design

In SEASIDE CHINA, all patients (N=330; N=318 adults, N=12 adolescents) had AD (IGA ≥3, EASI ≥16, BSA ≥10%, PP-NRS ≥4) inadequately controlled topically, no prior anti-IL-4Rα/IL-13s, and no concomitant topical AD therapy, except for rescue therapy and emollient.

Patients were randomized 2:1 to receive rademikibart 300 mg Q2W or placebo for 16 weeks in Stage 1 (Figure 1). Week 16 EASI-50 responders, regardless of treatment, were re-randomized 1:1 to receive rademikibart 300 mg Q2W (N=113) or Q4W (N=112) in Stage 2. Week 16 EASI-50 non-responders (N=86) received rademikibart Q2W in Stage 2.

**Figure 1:** The SEASIDE CHINA randomized, double-blind, pivotal trial



\*Achieved all primary and secondary endpoints.<sup>7-10</sup> †Blinding maintained with placebo between Q4W doses. ‡Open label.

### Statistics

Binary response was analyzed in: Stage 1 using CMH test, with missing data imputed by J2R (after the rule of intercurrent event) for rademikibart and MI for placebo; Stage 2 using NRI and MI. Continuous score change was analyzed using MMRM in Stage 1 and ANCOVA with MI (WOFC for non-responders) in Stage 2.

## Results

### Baseline disease characteristics

All patients had moderate-to-severe AD at baseline (Table 1).

**Table 1: Baseline characteristics for patients who entered Stage 2**

Characteristic at baseline in Stage 1*	Week 16 EASI-50 responders (Q2W in Stage 2) N=113	Week 16 EASI-50 responders (Q4W in Stage 2) N=112	Week 16 EASI-50 non-responders (Q2W in Stage 2) N=86
IGA 3 (moderate)	49 (43%)	53 (47%)	42 (49%)
IGA 4 (severe)	64 (57%)	59 (53%)	44 (51%)
EASI score	26.3 (16, 67)	26.4 (16, 72)	23.7 (16, 67)
PP-NRS score	6.9 (3, 10)	7.0 (2, 10)	7.6 (3, 10)
DLQI score	15.0 (1, 30)	14.0 (1, 30)	17.0 (1, 30)
POEM score	22.0 (6, 28)	22.0 (6, 28)	23.5 (6, 28)

\*IGA = n (%), EASI, PP-NRS, DLQI, and POEM score changes = median (min, max).

### High treatment completion rates

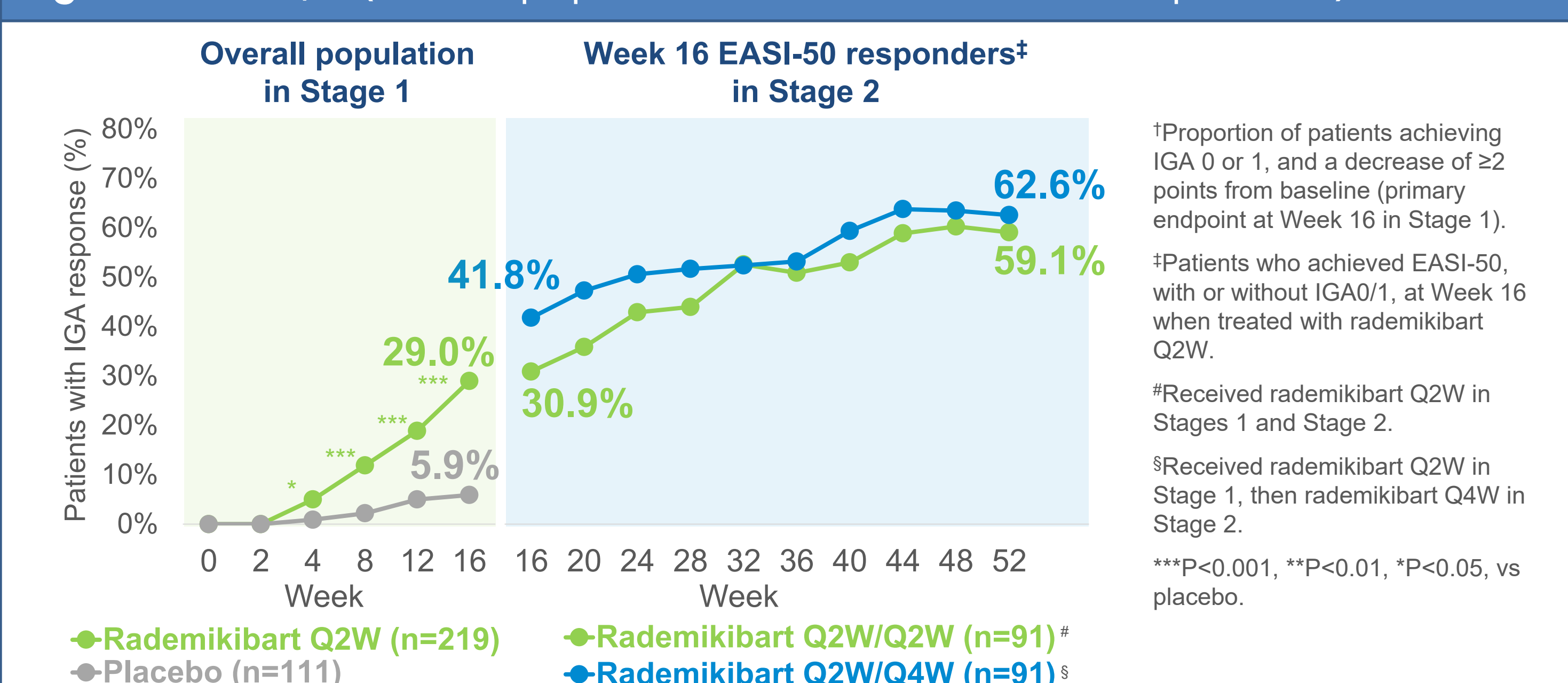
Most of these patients completed treatment, both in Stage 1 (95.4% rademikibart, 91.9% placebo) and in Stage 2 (92.4% rademikibart).

### Investigator-assessed efficacy outcomes

Improvements were observed across a range of investigator-rated AD scores during Stage 1 (16 weeks), including IGA, EASI, BSA, and SCORAD.

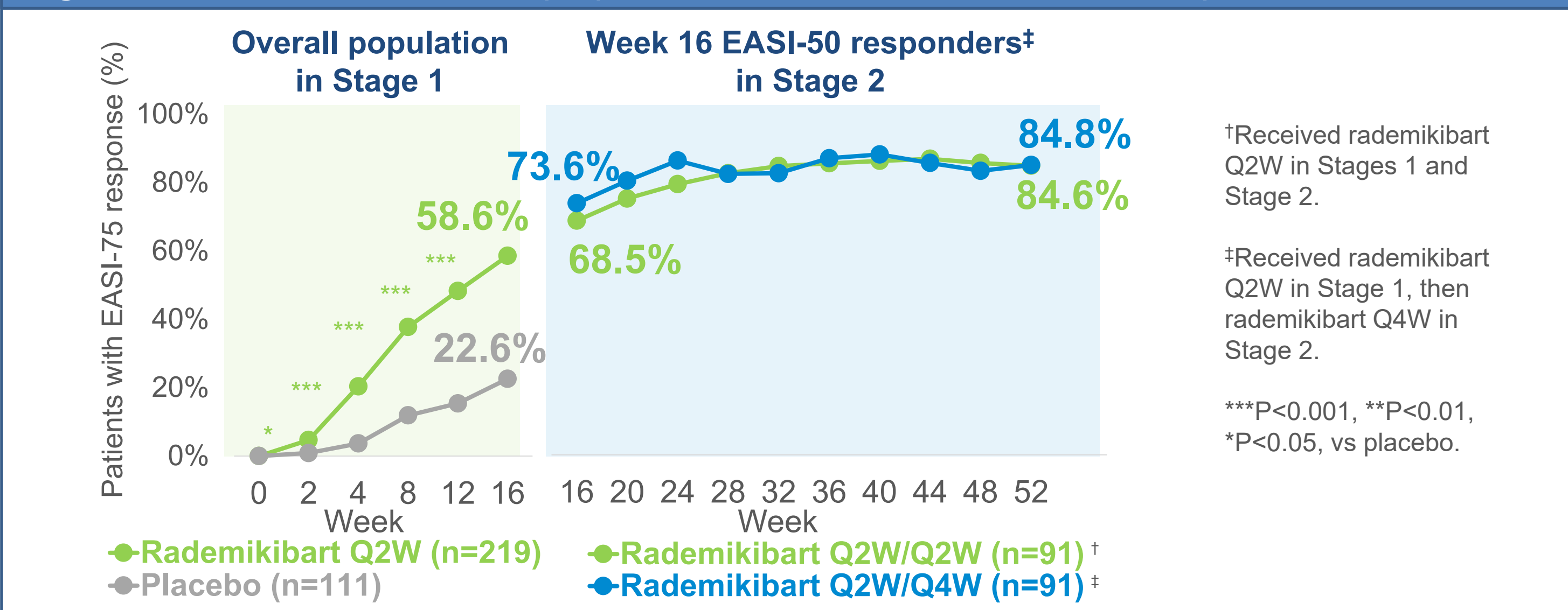
For Week 16 EASI-50 responders, AD signs continued to improve during Stage 2 (36 weeks) and, notably, were similar with Q2W and Q4W dosing (Figures 2-4).

**Figure 2:** IGA0/1† (overall population & Week 16 EASI-50 responders)



†Proportion of patients achieving IGA 0 or 1, and a decrease of ≥2 points from baseline (primary endpoint at Week 16 in Stage 1).  
\*Patients who achieved EASI-50, with or without IGA0/1, at Week 16 when treated with rademikibart Q2W.  
\*Received rademikibart Q2W in Stages 1 and Stage 2.  
\*Received rademikibart Q2W in Stage 1, then rademikibart Q4W in Stage 2.  
\*\*\*P<0.001, \*\*P<0.01, \*P<0.05, vs placebo.

**Figure 3:** EASI-75 (overall population & Week 16 EASI-50 responders)

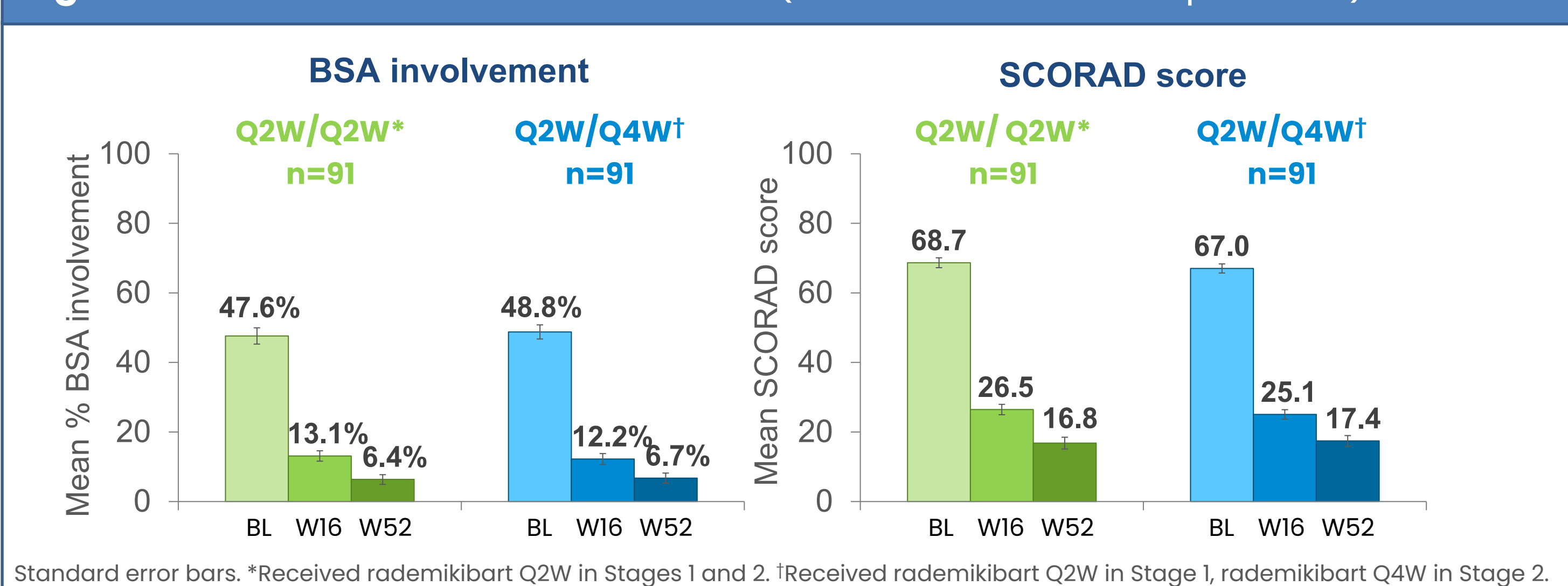


†Received rademikibart Q2W in Stages 1 and Stage 2.

†Received rademikibart Q2W in Stage 1, then rademikibart Q4W in Stage 2.

\*\*\*P<0.001, \*\*P<0.01, \*P<0.05, vs placebo.

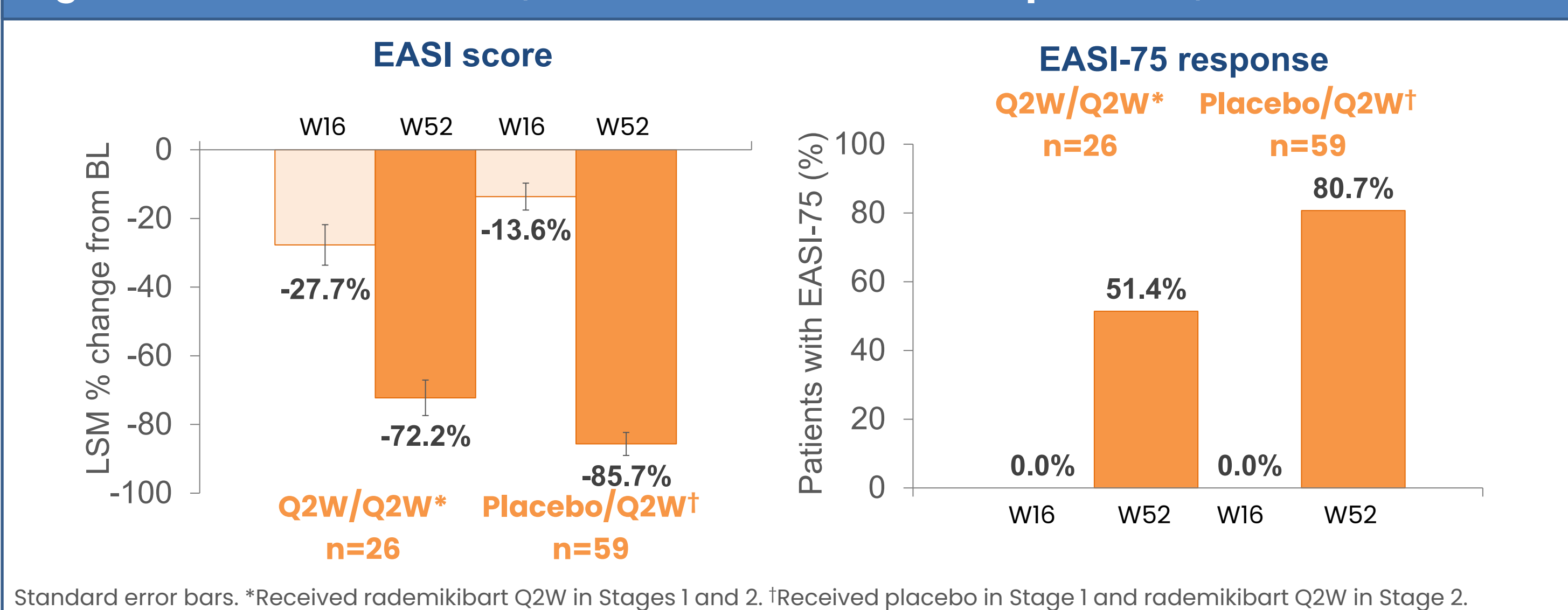
**Figure 4:** BSA involvement & SCORAD (Week 16 EASI-50 responders)



Standard error bars. \*Received rademikibart Q2W in Stages 1 and 2. †Received rademikibart Q2W in Stage 1, rademikibart Q4W in Stage 2.

Week 16 EASI-50 **non-responders** also experienced improvements across a range of AD rating scales during Stage 2, including EASI (Figure 5).

**Figure 5:** EASI & EASI-75 (Week 16 EASI-50 **non-responders**)

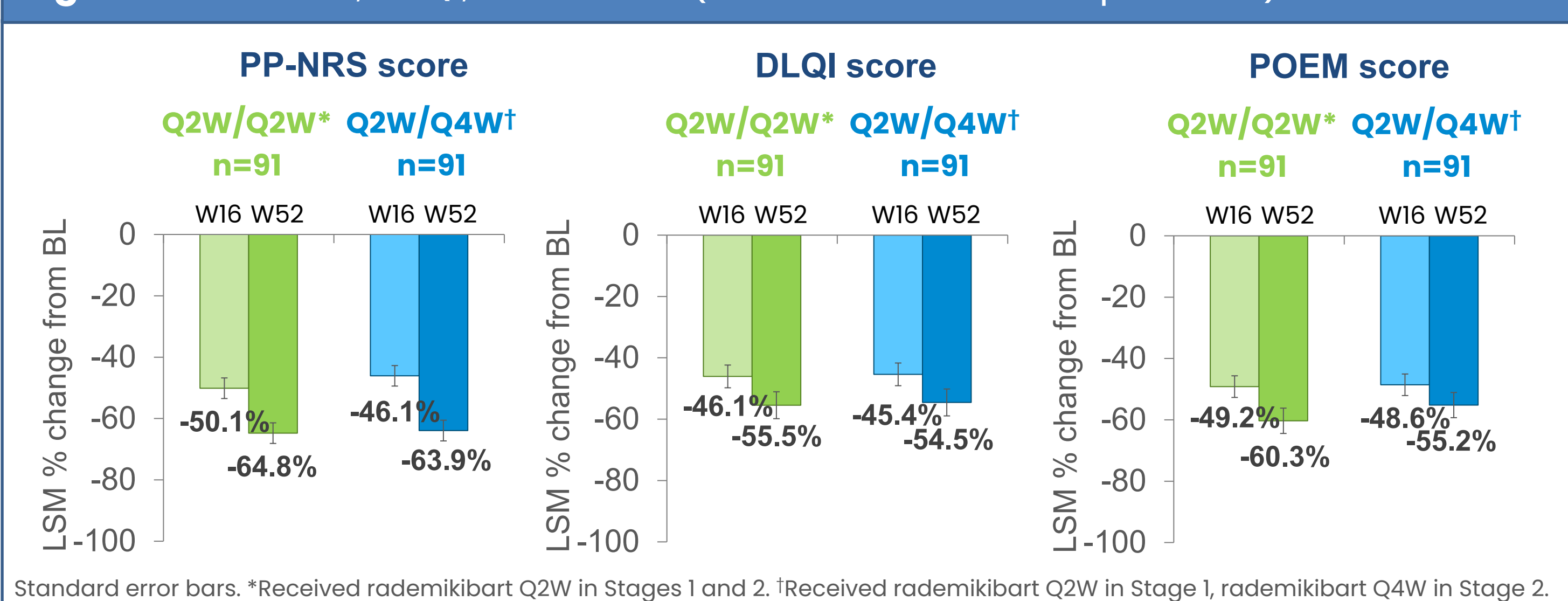


Standard error bars. \*Received rademikibart Q2W in Stages 1 and 2. †Received placebo in Stage 1 and rademikibart Q2W in Stage 2.

### Patient-reported efficacy outcomes

Continued improvement occurred across a range of patient-reported outcomes from Stage 1 through 2, with similar efficacy with Q2W and Q4W dosing (Figure 6).

**Figure 6:** PP-NRS, DLQI, and POEM (Week 16 EASI-50 responders)



Standard error bars. \*Received rademikibart Q2W in Stages 1 and 2. †Received rademikibart Q2W in Stage 1, rademikibart Q4W in Stage 2.

### Safety outcomes

No treatment-related serious TEAEs were observed. Two TEAEs led to rademikibart discontinuation in Stage 2; pregnancy (classified as a TEAE) and moderate vitiligo. All injection site reactions were mild and reported by 6.5% of patients in Stage 2.

## Conclusions

- Additional improvements in AD were gained with prolonged rademikibart treatment across Stage 2 (Weeks 16-52). These long-term efficacy findings are striking, and further bolster published rapid improvements across Stage 1.<sup>7-11</sup>
- Long-term efficacy was high with convenient Q4W dosing, and similar to Q2W.
- The minority of patients initially without clinically meaningful response (Week 16 EASI-50 non-responders) responded with long-term rademikibart Q2W dosing.
- Improvements were demonstrated with both investigator- and patient-reported outcomes. These sustained and clinically meaningful improvements in skin clearance, pruritus, and quality of life underscore the comprehensive benefits of long-term continuous therapy.

**Presented at:** EADV 2024, September 25<sup>th</sup>-28<sup>th</sup>, 2024, Amsterdam. **Funding:** Connect Biopharma.

**References:** 1. Yang et al. SID 2022, Portland, OR (Poster LB945). 2. Zhang et al. Sci Rep. 2023;13:12411. 3. Strober et al. Maui Derm 2022, Maui, HI. 4. Silverberg et al. J Allergy Clin Immunol. 2024;153:1040-9. 5. Strober et al. Poster P0215 (Abstract 470), EADV 2022, Milan, Italy. 6. Wang et al. Clin Transl Sci 2023;16:2614-27. 7. Zhang et al. Poster 3240, WCD 2023, Singapore. 8. Zhang et al. Poster 3242, WCD 2023, Singapore. 9. Zhang et al. Poster 3243, WCD 2023, Singapore. 10. Zhang et al. Poster 3247, WCD 2023, Singapore. 11. Zhang et al. Oral presentation #45874, AAD 2023, New Orleans, LA.

**Abbreviations:** AD, atopic dermatitis; ANCOVA, analysis of covariance; BL, baseline; BSA, Body Surface Area; CMH, Cochran-Mantel-Haenszel; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EASI-50/75, ≥50%/75% EASI score decrease from baseline; IGA, Investigator Global Assessment; J2R, jump to reference; LSM, least squares mean; mAb, monoclonal antibody; MI, multiple imputation; MMRM, Mixed-Effect Model for Repeated Measures; NRI, non-responder imputation; POEM, Patient Oriented Eczema Measure; PP-NRS, Peak Pruritus Numeric Rating Scale; Q2W/Q4W, every 2/4 weeks; R, randomized; SCORAD, SCORing AD; TEAE, treatment-emergent adverse event; WOFC, worst observation carried forward; W, week.