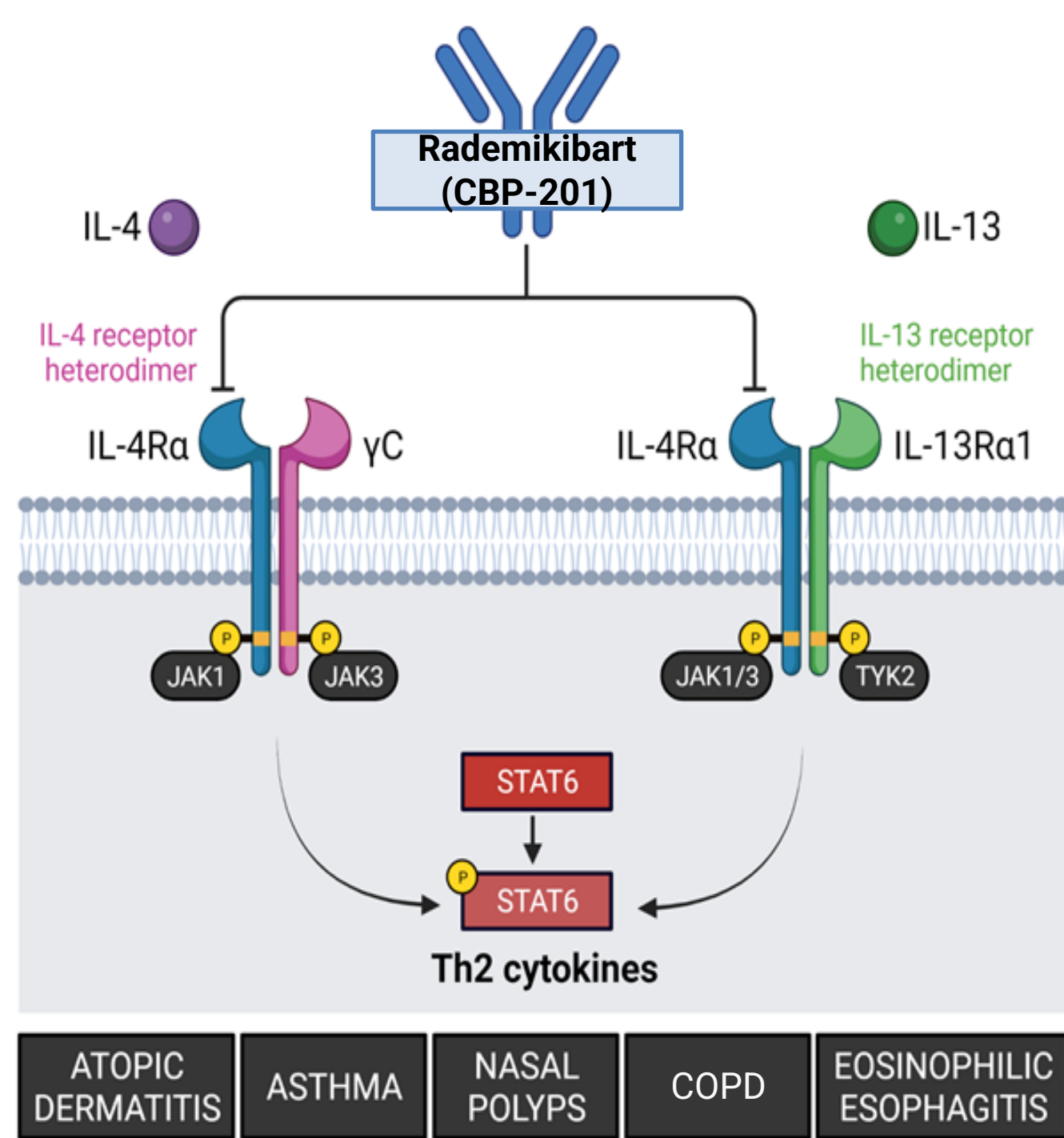


# Maintenance of Investigator and Patient Reported Outcomes over 52 Weeks were Observed with Rademikibart in Patients with Moderate-to-Severe Atopic Dermatitis (SEASIDE CHINA)

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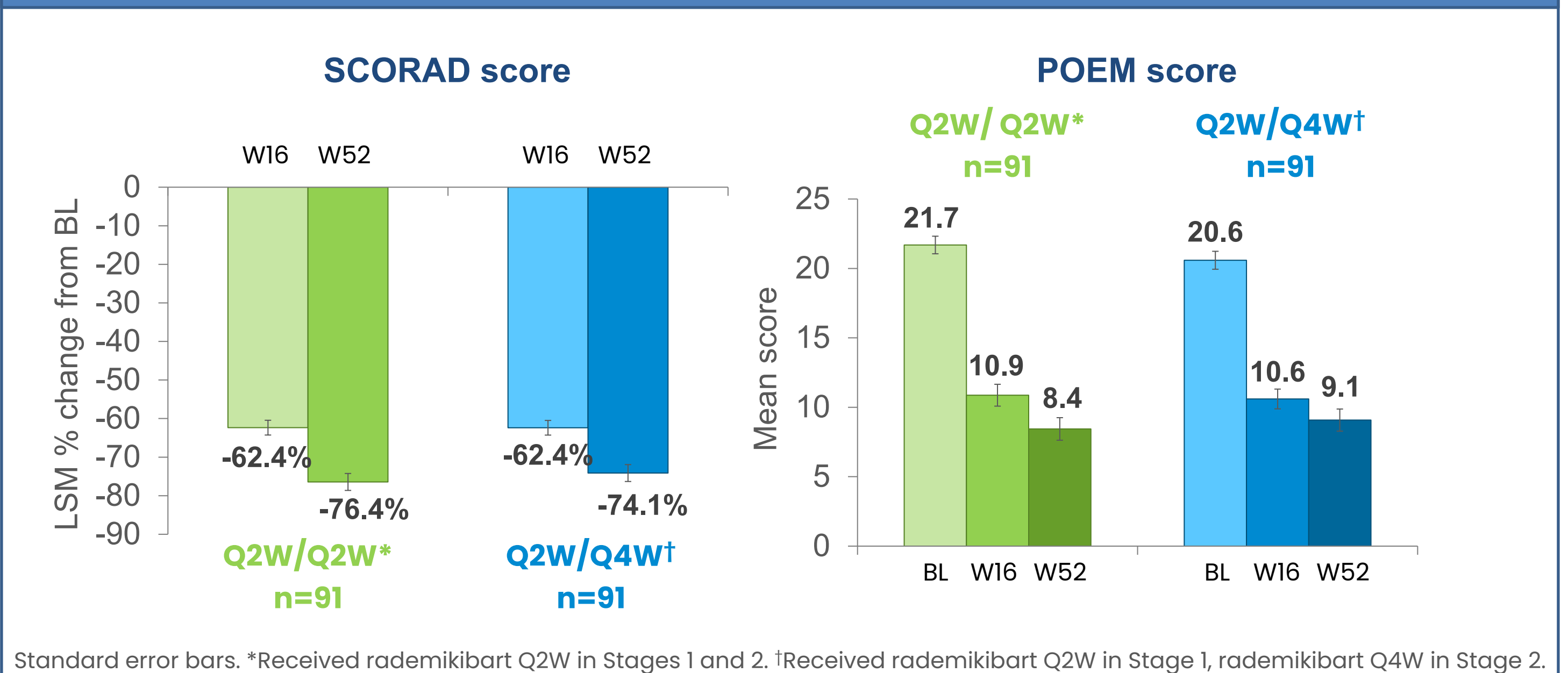
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- Rademikibart (formerly CBP-201), a next-generation mAb, binds with higher affinity to distinct IL-4Rα epitopes, compared with dupilumab.<sup>1,2</sup>
- IL-4 and IL-13 mediated responses are potentially inhibited by rademikibart.<sup>1,2</sup>
- Rademikibart therapy resulted in large improvements in AD lesions, pruritus, and quality of life in global and China-specific clinical trials.<sup>3-11</sup>
- The SEASIDE CHINA pivotal trial (CN002; NCT05017480) achieved its primary endpoint (IGA 0/1 and ≥2-point reduction from baseline) and all secondary endpoints at Week 16 of rademikibart treatment for patients with moderate-to-severe AD.<sup>7-11</sup>

**Figure 3:** SCORAD and POEM improvements were maintained in Stage 2

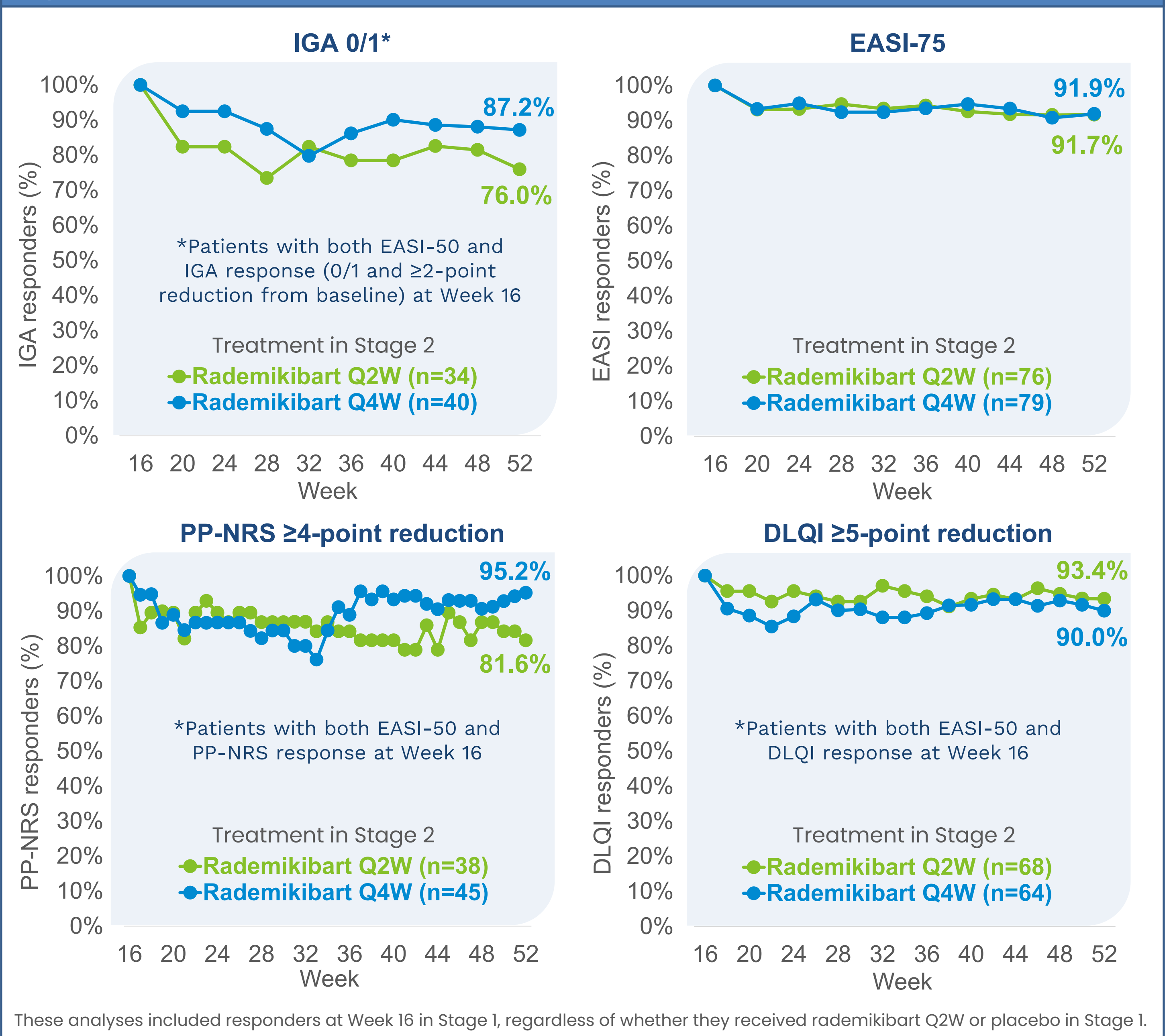


## Responders in Stage 1 maintained responses throughout Stage 2

Of patients achieving binary response criteria at Week 16 in Stage 1, most of these responders benefitted from maintenance of the response criteria through Week 52 in Stage 2 (Figure 4).

Notably, response maintenance rates in Stage 2 were similar with Q4W and Q2W dosing (Figure 4).

**Figure 4:** Maintenance of binary response in Stage 2



These analyses included responders at Week 16 in Stage 1, regardless of whether they received rademikibart Q2W or placebo in Stage 1.

## Objective

For the SEASIDE CHINA pivotal trial, we now report highly maintained responses across Stage 2 (36 weeks), in responders from Stage 1 (16 weeks). As well as high response maintenance, we report that patients gained further improvements in AD during Stage 2, building on previously reported meaningful improvements through Stage 1.<sup>7-11</sup>

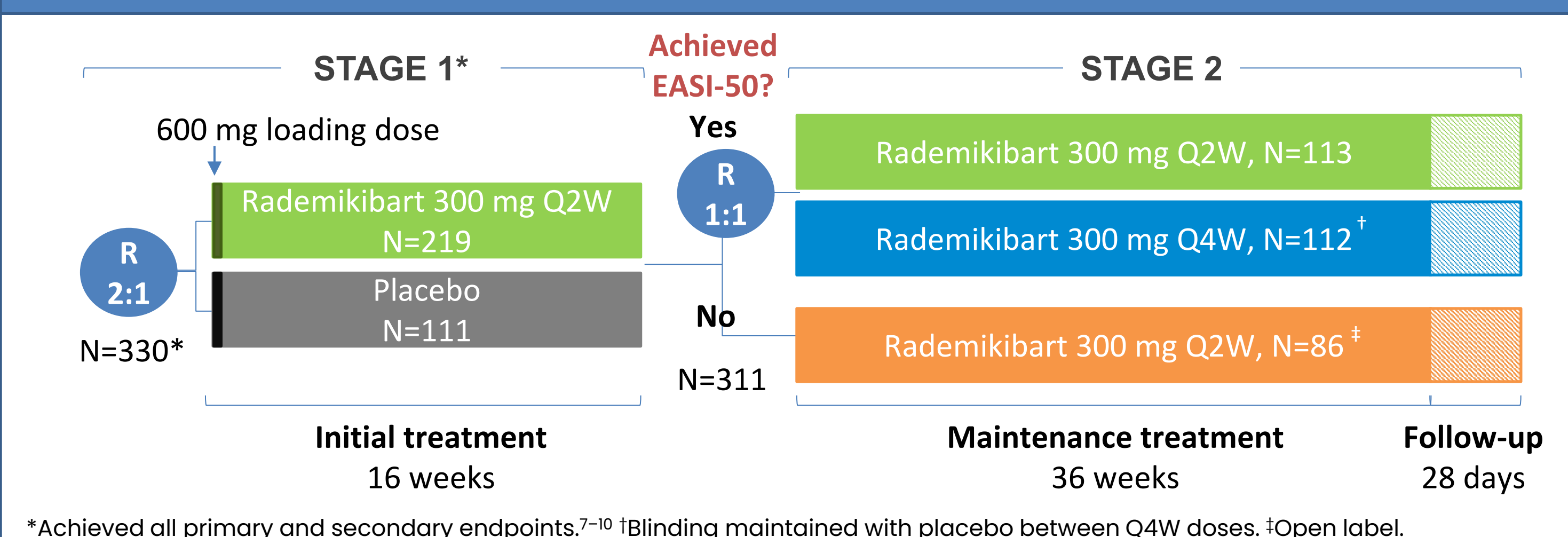
## Methodology

### 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



### 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 (WOCF for non-responders) in Stage 2.

## Results

### Baseline disease characteristics

All patients had moderate-to-severe AD at baseline, with characteristics that were generally balanced across the treatment groups. At baseline, patients who subsequently gained EASI-50 response at Week 16 in Stage 1, and entered Stage 2, had:

- Mean EASI score: 29.3 (range, 16.0–72.0)
- Mean PP-NRS score: 7.1 (range, 2.1–10.0)
- Mean BSA involvement score: 47.7% (range, 13.5–100.0)
- IGA score: 3 or 4 (45.3% and 54.7% of patients, respectively)

### High treatment completion rates

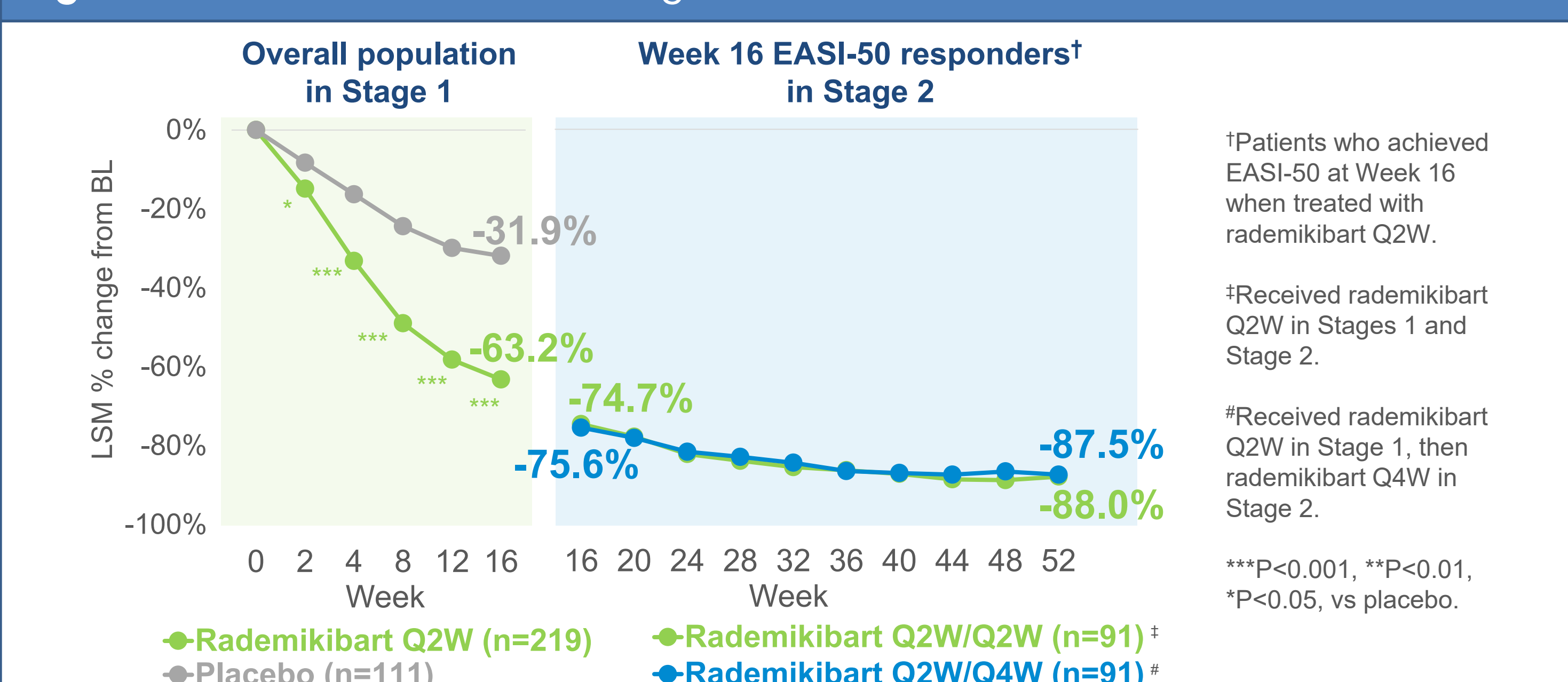
The proportions of patients completing treatment were 95.4% (rademikibart Q2W) and 91.9% (placebo) in Stage 1, and 92.4% (rademikibart Q4W or Q2W) in Stage 2.

### Improvements in AD, observed in Stage 1, continued during Stage 2

All efficacy rating scales used in SEASIDE CHINA demonstrated that, in Stage 1, AD signs and symptoms improved rapidly through 16 weeks of rademikibart Q2W therapy and, in Stage 2, improved further through 52 weeks. An example, BSA involvement, is shown in Figure 2.

All efficacy rating scales also demonstrated that AD improvements in Stage 2 were similar with Q4W and Q2W dosing (Figures 2 and 3).

**Figure 2:** BSA involvement in Stages 1 and 2



\*Patients who achieved EASI-50 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.

### Safety outcomes

No safety concerns were identified in Stage 2, compared with Stage 1 and with other clinical trials of rademikibart.<sup>7-11</sup>

- No treatment-related serious TEAEs were observed throughout the study.
- Two TEAEs led to rademikibart discontinuation in Stage 2; pregnancy (classified as a TEAE) and Grade 2 vitiligo. This was in addition to two TEAEs that led to treatment discontinuation in Stage 1, both AD flares (Grade 2 in the rademikibart Q2W arm and Grade 3 in the placebo arm).
- All injection site reactions were Grade 1 in intensity and, in Stage 2, affected 6.5% of patients.

## Conclusions

- Most patients with investigator- or patient-assessed responses at Week 16 of rademikibart therapy (Stage 1) maintained these responses through Week 52 (Stage 2).
- Patients also experienced continuous improvements in all AD rating scales (such as BSA involvement, Figure 2) throughout both Stages 1 and 2.
- Notably, efficacy was comparable with convenient Q4W and Q2W dosing, when administered in Stage 2.
- These compelling Stage 2 results, which build upon previously reported strong Stage 1 findings,<sup>7-11</sup> demonstrate that patients benefited from sustained and clinically meaningful improvements in skin clearance, pruritus and quality of life throughout one year of treatment with rademikibart.

**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-50/75/90, ≥50%/75%/90% 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; WOCF, worst observation carried forward; W, week.