

Topic: Atopic dermatitis/Eczema

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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Introduction & Objectives: Rademikibart (formally, CBP-201) is a next-generation monoclonal antibody targeting the IL-4R α subunit. Rademikibart achieved all Week 16 primary and secondary endpoints in a global Phase 2 atopic dermatitis (AD) trial (WW001; NCT04444752) and a pivotal trial in China (SEASIDE CHINA or CN002; NCT05017480)¹ in patients with moderate-to-severe AD. In this abstract, we now report Stage 2, long-term 52-week data from both investigator and patient reported outcomes from the SEASIDE CHINA pivotal trial.

Materials & Methods: Adults (n=318) and adolescents (n=12) (IGA \geq 3, EASI \geq 16, BSA \geq 10%, PP-NRS \geq 4) were randomized (2:1) to rademikibart (300mg Q2W) or placebo for 16 weeks (Stage-1). EASI-50 responders, regardless of Stage 1 treatment, were re-randomized to Q2W (n=113) or Q4W rademikibart (n=112). Non-responders received open-label Q2W rademikibart (n=86).

Results: The initial baseline measurements revealed a mean EASI score of 29.3 (ranging from 16.0 to 72.0), a mean PP-NRS score of 7.1 (2.1 to 10.0), and a mean BSA involvement of 47.7% (13.5 to 100.0) among Stage 1 responders, with 54.7% classified as having an IGA score of 4. For non-responders, the respective measurements were 23.7 (ranging from 16.0 to 66.6) for EASI, 7.4 (ranging from 3.1 to 10.0) for PP-NRS, and 48.0% (ranging from 13.0 to 100.0) for BSA involvement, with 51.2% categorized as IGA 4.

For investigator reported outcomes, the numbers of patients achieving IGA 0/1 (n=74) and EASI-75 (n=155) response were examined. In patients who achieved IGA 0/1 at the end of Stage 1, 76.0% (Q2W) and 87.2% (Q4W) maintained their response at Week 52. Similarly, 91.7% (Q2W) and 91.9% (Q4W) maintained their EASI-75 response from the end of Stage 1. The percent improvement from baseline in BSA involvement at Week 16 and Week 52 respectively were -74.7% and -88.0% (Q2W) and -75.6% and -87.5% (Q4W). Similarly, the respective percent improvement from baseline for the clinical tool, SCORAD, was -62.4% and -76.4% (Q2W) and -62.4% and -74.1% (Q4W).

For patient reported outcomes, patients with a \geq 4-point reduction in PP-NRS, 81.6% (Q2W) and 95.2% (Q4W) maintained that response at Week 52. A clinically meaningful \geq 5-point reduction on the DLQI was maintained by 93.4% (Q2W) and 90.0% (Q4W). Additionally, for scores on the POEM, the absolute change from baseline at Week 16 and Week 52 respectively was maintained: -9.5 vs -12.4 (Q2W) and -9.8 vs -12.2 (Q4W) respectively. Treatment with rademikibart was generally well tolerated.

Conclusion: Maintenance data with rademikibart are compelling and build upon strong results shown in Stage 1¹. The observed efficacy remains consistently high with a convenient Q4W dosing during the maintenance period with both investigator and patient reported outcomes demonstrating sustained clinically meaningful changes in skin clearance, pruritus and quality of life.

