

Topic: Atopic dermatitis/Eczema

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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Introduction & Objectives: Rademikibart (formally, CBP-201) is a next-generation, high affinity, monoclonal antibody targeting the IL-4R α subunit. Rademikibart achieved all Week 16 (Stage 1) primary and secondary endpoints in an atopic dermatitis (AD) pivotal trial in China (SEASIDE CHINA or CN002; NCT05017480) in patients with moderate-to-severe AD. In this report, we describe the continuing efficacy improvement during the Stage 2, long-term 52-week period 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 (n=86) received open-label Q2W rademikibart during Stage 2.

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.

From Week 16 to Week 52, 28.2% (Q2W/Q2W; n=91) and 20.8% (Q2W/Q4W; n=91) additional patients achieved IGA 0/1, and additional patients achieving EASI-75 was 16.3% and 11.0%, respectively. The change from baseline in BSA involvement also continued to improve from -34.7% to -41.3% and from -35.8% to -41.2%, respectively. Similarly, the respective improvement from baseline for SCORAD improved from -41.8 to -51.5 and from -42.5 to -50.2. For 26 rademikibart non-responders from Stage 1, EASI scores improved by 45% with 51.4% achieving EASI-75 by Week 52. Treatment with rademikibart was generally well tolerated.

Patient reported outcomes also continued to improve. The percent change from baseline in PP-NRS improved from a change of -50.1% to -64.8% (Q2W/Q2W) and from -46.1% to -63.9% (Q2W/Q4W) for the two treatment groups. For PEOM scores, the percent change from baseline continued to improved from -49.2% to -60.3% and from -48.6% to -55.2%, respectively. Similarly, DLQI percent change from baseline continued to improve from -46.1% to -55.5% and from -45.4% to -54.5%, respectively.

Conclusion: The maintenance data with rademikibart are striking, further bolstering the robust findings seen in Stage 1. Notably, the efficacy remains consistently high with a convenient Q4W dosing, and there are additional improvements observed with prolonged treatment. Moreover, both investigator and patient reported outcomes demonstrate sustained clinically meaningful changes in skin clearance, pruritus and quality of life, underscoring the comprehensive benefits of continued therapy.

