

Positive 52-week maintenance data observed with rademikibart in patients with moderate-to-severe atopic dermatitis (SEASIDE CHINA)

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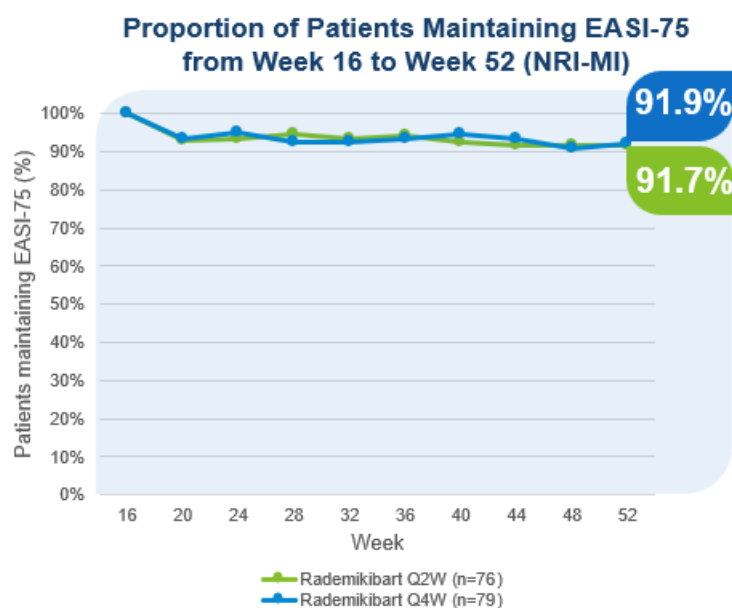
Introduction/Background: Rademikibart (formally, CBP-201) is a next-generation optimized monoclonal antibody targeting the IL-4R α subunit. Rademikibart achieved all Week 16 primary and secondary endpoints in a global Phase 2 atopic dermatitis (AD) trial (WW001; NCT04444752) and a pivotal trial in China (SEASIDE CHINA or CN002; NCT05017480)¹ in patients with moderate-to-severe AD.

Objectives: Long-term treatment of atopic dermatitis is essential for continued symptom management, prevention of complications, and improvements in the patient's quality of life. In this report, we now report Stage 2, long-term 52-week data from the SEASIDE CHINA pivotal trial.

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: Initial baseline mean EASI was 29.3 (range, 16.0–72.0) with 54.7% IGA4 for Stage 1 responders and 23.7 (16.0-66.6) with 51.2% respectively for non-responders. In patients who achieved IGA 0/1, 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 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 16.3% (Q2W/Q2W) and 11.0% (Q2W/Q4W) additional patients achieved EASI-75. Of patients with \geq 4-point reduction in PP-NRS, 81.6% (Q2W) and 95.2% (Q4W) maintained that response at Week 52. A \geq 5-point reduction on the DLQI was maintained by 93.4% (Q2W) and 90.0% (Q4W). For 26 rademikibart non-responders (Stage-1), EASI scores improved by 45% with 51.4% achieving EASI-75 by Week 52. Treatment with rademikibart was generally well tolerated.

Conclusion: Maintenance data with rademikibart are compelling and build upon strong results shown in Stage 1¹. High rates of maintained efficacy with Q4W dosing, additional gains in efficacy with continued treatment, and maintenance of clinically meaningful changes in pruritus and QOL were observed.



Keywords: moderate-to-severe atopic dermatitis, rademikibart, CBP-201, therapy, IL-4R α

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1. Zhang J, Silverberg JI, Li P, et al. CBP-201, a next-generation IL-4R α antibody, achieved all primary and secondary efficacy endpoints, with a favorable safety profile, in adults with moderate-to-severe atopic dermatitis (AD): A randomized, double-blind, pivotal trial in China (CBP-201-CN002). Oral presentation #45874, 2023 Annual Meeting of the American Academy of Dermatology (AAD 2023); New Orleans, LA, USA.