

CBP-201, a next-generation IL-4R α antibody, achieved all primary and key secondary endpoints in a randomized pivotal trial for moderate-to-severe atopic dermatitis (AD) in China (CBP-201-CN002)

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Introduction: CBP-201 achieved its primary and key secondary endpoints in a global phase 2 study of patients with moderate-to-severe AD (NCT04444752). We subsequently evaluated CBP-201 in a pivotal AD trial in China (NCT05017480).

Objectives: To report key outcomes from the pivotal trial in China.

Materials and Method: 255 patients were randomized (2:1) to CBP-201 (600 mg loading dose, followed by 300 mg Q2W) or placebo for 16 weeks. Eligible patients had AD (IGA ≥ 3 , EASI ≥ 16 , BSA $\geq 10\%$, PP-NRS ≥ 4) inadequately controlled topically, no prior anti-IL-4R α /IL-13s, and no concomitant topical AD treatment except rescue medication and emollient. Missing data were imputed with jump to reference and multiple imputation for CBP-201 and placebo, respectively.

Results: At baseline, median EASI was 26.9 (range 16.0–72.0), IGA4 54.5%. The proportion of patients achieving IGA 0-1 and ≥ 2 -point reduction was greater with CBP-201 (30.3%) vs placebo (7.5%; $p < 0.001$) at Week 16 (primary endpoint). Greater proportions of patients achieved EASI reductions with CBP-201 than placebo (EASI-75, 62.9% vs 23.4% [$p < 0.001$]; EASI-90, 35.8% vs 6.3% [$p < 0.001$]) at Week 16. LS mean PP-NRS changes (-38.1% vs -12.3%; $p < 0.001$) and the proportions of patients with ≥ 3 -point (46.7% vs 16.7%; $p < 0.001$) and ≥ 4 -point reductions (35.0% vs 9.6%; $p < 0.001$) were greater with CBP-201 than placebo at Week 16. DLQI improved by -35.7% (CBP-201) vs -9.0% (placebo; $p < 0.001$) at Week 16. Statistically significant improvements in scores began as early as Week 1. IGA and EASI responses had not plateaued by Week 16. CBP-201 had favorable safety and tolerability profiles.

Conclusions: This pivotal trial of CBP-201 in China achieved its primary and secondary endpoints; rapid and sustained improvements were observed in AD (including pruritus), without reaching a plateau, indicating potential for further improvement beyond 16 weeks. Improvements in objective skin measurements were mirrored by patient-reported benefits on quality of life.