

Improvements in investigator-rated outcomes across 16 weeks of treatment with CBP-201 for moderate-to-severe atopic dermatitis (AD): Results from a pivotal trial in China (CBP-201-CN002)

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Introduction: CBP-201, a next-generation monoclonal IL-4R α antibody, 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 investigate the time course of improvements in investigator-rated outcomes across 16 weeks of treatment with CBP-201 in the pivotal trial in China.

Materials and Method: 255 patients with moderate-to-severe AD were randomized (2:1) to CBP-201 (600 mg loading dose, followed by 300 mg Q2W) or placebo. Investigators assessed AD severity using Investigator's Global Assessment (IGA), EASI, percent body surface area (BSA) involvement, and SCORing AD (SCORAD). SCORAD includes investigator-assessed AD severity and patient-assessed itch and sleep.

Results: Rapid and sustained improvements were observed in investigator-rated efficacy outcomes with CBP-201 vs placebo. At Weeks 4, 8, and 16, the proportions of patients with IGA responses (0/1 and ≥ 2 -point reduction from baseline), with CBP-201 vs placebo, were 4.7% vs 0% ($p < 0.01$), 11.2% vs 2.4% ($p < 0.01$), and 30.3% vs 7.5% ($p < 0.001$). At Weeks 4, 8, and 16, 20.1% vs 3.5% ($p < 0.001$), 37.7% vs 11.8% ($p < 0.001$), and 62.9% vs 23.4% ($p < 0.001$) achieved EASI-75 with CBP-201 vs placebo, and 5.4% vs 2.4% ($p = 0.2$), 15.2% vs 2.4% ($p < 0.001$), and 35.8% vs 6.3% ($p < 0.001$) achieved EASI-90. Reductions in LS mean scores with CBP-201 vs placebo at Weeks 2, 4, and 16 were: SCORAD -19.1% vs -8.8% ($p < 0.001$), -33.5% vs -14.8% ($p < 0.001$), and -55.5% vs -25.5% ($p < 0.001$); BSA -15.8% vs -8.6% ($p = 0.01$), -33.3% vs -16.5% ($p < 0.001$), and -66.4% vs -33.3% ($p < 0.001$), respectively.

Conclusions: Investigators reported rapid and sustained improvements in AD across 16 weeks of treatment with CBP-201. These reductions in investigator-assessed AD severity are mirrored by improvements in patient-reported outcomes and are confirmatory of data previously reported from the global phase 2 AD trial with CBP-201.