

CBP-201, a next-generation IL-4R α antibody, achieved all primary and secondary efficacy endpoints in the treatment of adults with moderate-to-severe atopic dermatitis (AD): A randomized, double-blind, pivotal trial in China (CBP-201-CN002)

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CBP-201 achieved its primary and secondary endpoints in a global Phase 2 AD trial (NCT04444752).¹⁻⁵ We report primary and secondary endpoints from a pivotal trial in China (NCT05017480).

255 adults in the primary population (IGA ≥ 3 , EASI ≥ 16 , BSA $\geq 10\%$, PP-NRS ≥ 4) were randomized (2:1) to CBP-201 (600mg loading, subsequently 300mg Q2W) or placebo, without concomitant topical therapy except emollient and rescue medication. Other eligibility criteria included no prior anti-IL-4R α /IL-13s and AD inadequately controlled topically.

At baseline, median EASI was 26.9 (range, 16.0–72.0), 54.5% IGA=4. At Week 16, greater proportions of patients treated with CBP-201 vs placebo ($p < 0.001$) achieved: IGA 0-1 and ≥ 2 -point reduction (30.3% vs 7.5%; primary endpoint); EASI-75 (62.9% vs 23.4%); EASI-90 (35.8% vs 6.3%); and PP-NRS reductions (≥ 3 -points, 46.7% vs 16.7%; ≥ 4 -points, 35.0% vs 9.6%). Least square mean PP-NRS reduction (38.1% vs 12.3%; $p < 0.001$) was greater with CBP-201 than placebo at Week 16. Significant efficacy improvements began as early as Week 1. IGA and EASI responses did not plateau. Proportions of patients reporting treatment-emergent adverse events (TEAEs), CBP-201 vs placebo, were: any (73.5% vs 72.9%), serious (0.6% vs 3.5%), severe (2.4% vs 5.9%), conjunctivitis (4.7% vs 3.5%), keratitis (1.2% vs 0%), injection-site reactions lasting > 24 h (6.5% vs 0%), anaphylaxis (0.6% vs 0%). Anaphylaxis was non-serious and unrelated to treatment. One patient discontinued CBP-201 owing to a TEAE (AD).

This pivotal AD trial of CBP-201 achieved all primary and secondary endpoints, without IGA and EASI responses plateauing at Week 16, compatible with the global Phase 2 trial.¹⁻⁵

References

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Disclosures

Jianzhong Zhang has no relevant financial relationships to disclose.

All other authors are current or former employees of Connect Biopharma.