Eczema Area and Severity Index (EASI) scores improved, with favorable safety and tolerability, across 16 weeks of treatment with CBP-201 for moderate-to-severe atopic dermatitis (AD) in China

Jianzhong Zhang,[1] Pauline Li,[2] Jiawang Guo,[2] Jili Yun,[2] Jang Yun,[3] Chin Lee,[3] Zheng Wei,[3] Wuban Pan,[2] Raúl Collazo[3]

[1]Peking University People's Hospital, Department of Dermatology, Beijing, China; [2]Suzhou Connect Biopharmaceuticals Ltd, Taicang, China; [3]Connect Biopharma LLC, San Diego, USA

Introduction: CBP-201, a next-generation monoclonal IL-4Rα antibody, demonstrated significant improvements in skin clearance, disease severity, and itch in our global Phase 2b trial in patients with moderate-to-severe AD (NCT04444752). Significant reductions were observed in EASI score at Week 16 (primary endpoint) in the global trial. We subsequently evaluated CBP-201 in a pivotal AD trial in China (NCT05017480).
Objectives: To report change in EASI scores (a secondary endpoint) and safety outcomes 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.
Results: At baseline, mean (SD) EASI scores were 29.6 (11.9) and 29.3 (12.0) in the CBP-201 and placebo arms. Significant improvements in EASI with CBP-201 vs placebo occurred at the earliest assessment (Week 2) and at each time point during the 16-week treatment period. Reductions in LS mean EASI scores with CBP-201 vs placebo at Weeks 2, 4, and 16 were: -26.3% vs -13.8% (p<0.001), -46.1% vs -21.6% (p<0.001), and -73.7% vs -36.6% (p<0.001). At Week 16, EASI score changes had not plateaued. For CBP-201 vs placebo, proportions of patients reporting treatment-emergent adverse events (TEAEs) were: any TEAE (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 hours (6.5% vs 0%), anaphylaxis (0.6% vs 0%). One patient discontinued CBP-201 owing to a TEAE (atopic dermatitis).
Conclusions: Patients experienced rapid and sustained improvements in AD across 16 weeks of CBP-201 therapy, without reaching a plateau, indicating potential for further improvement beyond 16 weeks of treatment with CBP-201. CBP-201 had favorable safety and tolerability profiles. The findings are confirmatory of outcomes previously reported from the global phase 2 AD trial.