CBP-201, a next-generation IL-4Rα 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)

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

[1]Peking University People's Hospital, Department of Dermatology, Beijing, China; [2]Suzhou Connect Biopharmaceuticals Ltd, Taicang, China; [4]Connect Biopharma LLC, San Diego, CA, USA

[[Word limit, excluding references: 250; Current number: 250]]

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 ≥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-4Rα/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 >24h (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

1. Strober B, Feinstein B, Xu J, et al. Efficacy and safety of CBP-201 in adults with moderate-to-severe atopic dermatitis: A phase 2b, randomized, double-blind, placebo-controlled trial (CBP-201-WW001). Poster presented at 18th Maui Derm 2022, Maui, HI, USA.
2. Silverberg J, Feinstein B, Guttman-Yassky E, et al. The effect of baseline disease characteristics of efficacy outcomes: Results from a phase 2b, randomized, double-blind, placebo-controlled trial (CBP-201-WW001). Poster presented at 18th Maui Derm 2022, Maui, HI, USA.
3. Silverberg J, Strober B, Guttman-Yassky E, et al. Disease control and quality of life: Efficacy outcomes from the phase 2b trial of CBP-201 in patients with atopic dermatitis (CBP-201-WW001). Poster #252 presented at RAD April 2022.
4. Strober B, Silverberg J, Guttman-Yassky E, et al. Investigator-rated efficacy outcomes across 16 weeks of treatment with CBP-201: Results from a phase 2b trial in patients with atopic dermatitis (CBP-201-WW001). Poster presented at EADV 2022, Milan, Italy.

5. Silverberg J, Strober B, Guttman-Yassky E, et al. Patient-reported efficacy outcomes across 16 weeks of treatment with CBP-201: Results from a phase 2b trial in patients with atopic dermatitis (CBP-201-WW001). Poster presented at EADV 2022, Milan, Italy.

Disclosures

Jianzhong Zhang has no relevant financial relationships to disclose.

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