Improvements in patient-reported outcomes (PROs) 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-4Rα 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 PROs 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. Patient-reported itching was assessed using the Peak Pruritus Numerical Rating Scale (PP-NRS). Itching, other symptoms, and quality of life (QoL) were assessed using the Patient Oriented Eczema Measure (POEM) and Dermatology Life Quality Index (DLQI).

Results: Rapid improvements with each PRO, at the first assessment (Week 1 or 2), were subsequently sustained throughout the 16-week treatment period. Least squares (LS) mean reductions in PP-NRS scores with CBP-201 vs placebo at Weeks 1, 2, 4, and 16 were -8.6% vs -3.7% (p<0.05), -13.7% vs -6.0% (p<0.05), -26.6% vs -11.3% (p<0.001), and -38.1% vs -12.3% (p<0.001), respectively. At Weeks 2, 4, and 16, with CBP-201 vs placebo, LS mean reductions in: POEM scores were -12.9% vs +1.6% (p<0.001), -28.0% vs -5.4% (p<0.001), and -39.3% vs -7.4% (p<0.001); DLQI scores were -9.7% vs -2.6% (p=0.08), -23.2% vs -7.4% (p=0.001), and -35.7% vs -9.0% (p<0.001), respectively.

Conclusions: Patients reported rapid and sustained improvements in AD, including pruritus, and better QoL across 16 weeks of treatment with CBP-201. These patient-reported improvements are compatible with investigator-assessed findings, including reductions in the primary endpoint (proportion of patients with IGA 0/1 scores and ≥2-point reduction from baseline at Week 16) and a key secondary endpoint (EASI-75), and are confirmatory of data previously reported from the global phase 2 AD trial with CBP-201.