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)

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Introduction: CBP-201, a novel monoclonal antibody targeting IL-4Rα, recently met its primary and key secondary endpoints in the treatment of moderate-to-severe atopic dermatitis (AD) in a Phase 2b trial (WW001). All three doses of CBP-201 showed significant percent reductions in least square mean EASI scores at Week 16 (-63.0%; CBP-201 300mg Q2W), (-57.5%; 150mg Q2W) and (-65.4%; 300mg Q4W) vs placebo (-40.7%). Here, we present patient-reported efficacy outcomes across 16 weeks.

Materials and Methods: In WW001 (NCT04444752), 226 adults with moderate-to-severe AD were randomized (1:1:1:1), double-blind, to the three doses of subcutaneous CBP-201 or placebo. Patient-reported itching was assessed using the Peak Pruritus Numerical Rating Scale (PP-NRS; score 0–10). Itching, other symptoms, and quality of life (QoL) were assessed using the Patient Oriented Eczema Measure (POEM; score 0–28) and Dermatology Life Quality Index (DLQI; score 0–30). Higher scores indicate worse AD and QoL. Changes from baseline in scores are Observed Cases analyses.

Results: Baseline PP-NRS, POEM and DLQI scores were similar across the CBP-201 and placebo arms.

Rapid improvements were observed in mean POEM and DLQI scores in the CBP-201 arms (300mg Q2W, 150mg Q2W, 300mg Q4W) vs placebo. At Week 2, reductions in mean POEM scores were -25.9%, -27.9% and -22.7% vs -12.0%, respectively, and mean DLQI scores decreased by -23.5%, -29.8% and -27.4% vs -18.0%. POEM and DLQI scores continued to decrease across the 16-week treatment period, beginning to plateau between Weeks 4 and 8. At Week 16, reductions in mean POEM scores were -58.7%, -49.2% and -52.3% vs -32.0%, respectively, and mean DLQI scores decreased by -61.8%, -53.7% and -59.3% vs -38.1%. In post hoc analyses, there were higher proportions of patients with DLQI ≤5 points in the active arms across the 16-week treatment period, starting at Week 2, and significantly higher at Week 16 (54.4% [$p<0.01$], 49.1% [$p=0.03$], 48.2% [$p=0.03$] vs 28.6%).

There were also rapid increases in the proportions of patients with PP-NRS improvements in the CBP-201 arms (300mg Q2W, 150mg Q2W, 300mg Q4W) vs placebo. At Week 2, ≥3-point PP-NRS improvement were reported by 19.2%, 13.2% and 16.9% vs 9.4% of patients, respectively, and the proportions with ≥4-point improvements were 15.7%, 9.6% and 5.8% vs 3.8%. By Week 16, ≥3- and ≥4-point PP-NRS responses had increased further; ≥3-point improvements were reported by 50.0%, 39.6%, 45.3% vs 32.1% of patients, while the proportions with ≥4-point improvements were 47.1%, 26.9%, 33.3% vs 23.1%.

Conclusion: Patients with moderate-to-severe AD reported rapid reductions in symptoms and disease burden in the first 2 weeks of treatment with CBP-201, which were sustained across the 16-week treatment period during the WW001 Phase 2b trial. These patient-reported improvements are mirrored by reductions in investigator-assessed AD severity (see Strober et al, Maui Derm 2022) and are compatible with previously reported investigator-assessed findings in this trial, including reductions in the primary endpoint (EASI at Week 16). Additionally, these data demonstrate the possibility of a convenient, reliably efficacious 2- and 4-week dosing option not available with other biologic treatments for moderate-to-severe AD. CBP-201 300mg Q2W and 300mg Q4W dosing warrant further investigation in Phase 3.

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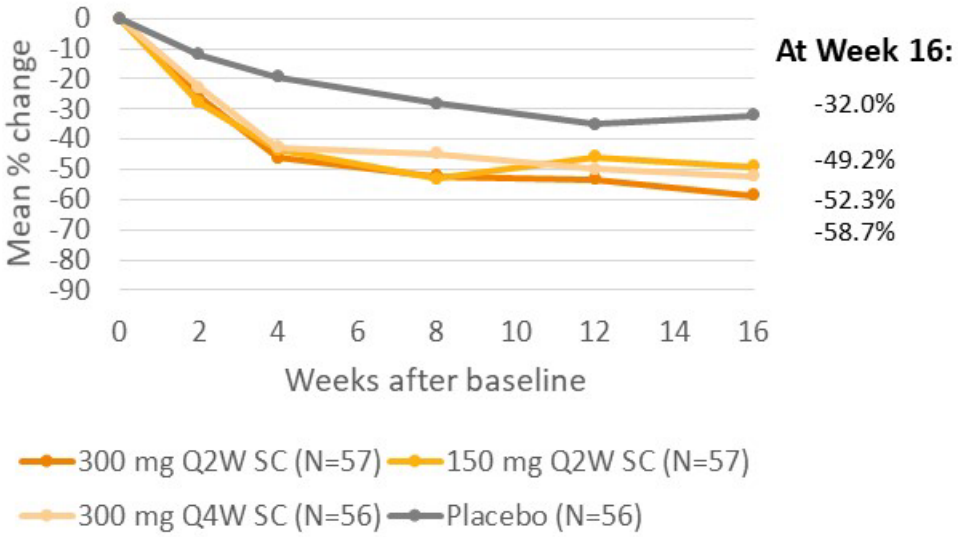
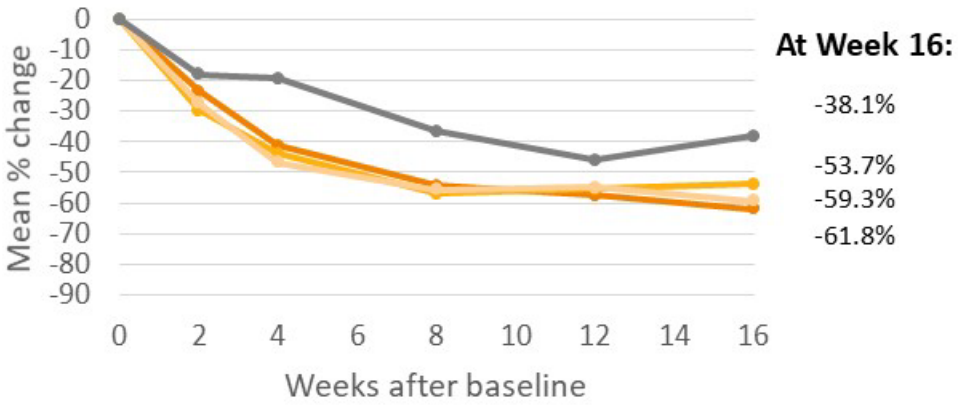
Efficacy outcomes in the overall population

Patient Oriented Eczema Measure (POEM; Observed Cases)



Dermatology Life Quality Index (DLQI; Observed Cases)



% patients with ≥3-point Peak Pruritus Numerical Rating Scale (PP-NRS) improvement