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)

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Introduction: CBP-201, a 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 (NCT04444752). All three doses of CBP-201 showed significant percent reductions in LS 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 investigator-rated efficacy outcomes across the 16-week treatment period.

Materials and Methods: 226 adults with moderate-to-severe AD were randomized (1:1:1:1), double-blind, to one of the three doses of CBP-201 or placebo. Investigators assessed the severity of AD using EASI (total score 0–72), SCORAD (total score 0–103), IGA (0-4) and BSA involvement. Higher scores indicate worse severity. The SCORAD total score includes both investigator-assessed AD severity and patient-assessed itch and sleep.

Results: Rapid improvements were observed in EASI, SCORAD and percent BSA involvement in the CBP-201 arms (300mg Q2W, 150mg Q2W, 300mg Q4W) vs placebo. At Week 2, mean EASI scores were, respectively, -28.0%, -20.7% and -24.0% vs -13.2% lower than at baseline, mean SCORAD scores decreased by -21.8%, -16.7% and -18.5% vs -9.5%, and mean percent BSA involvement decreased by -14.5%, -12.5% and -12.3% vs -9.5%. All three ratings decreased further throughout the 16-week treatment period in the CBP-201 arms vs placebo. At Week 16, mean EASI scores were, respectively, -63.6%, -57.6% and -63.0% vs -39.7% lower than at baseline, mean SCORAD scores decreased by -60.1%, -49.8% and -53.9% vs -37.8%, and mean percent BSA involvement decreased by -52.0%, -45.7% and -50.3% vs -25.7%. Improvements in median EASI scores and BSA involvement were greater than mean improvements with all three CBP-201 doses at Week 16, with similar median vs mean placebo responses; median reductions in EASI were -79.3%, -64.7% and -70.0% vs -41.0%, and median reductions in BSA were -61.3%, -61.0%, and -56.4% vs -22.2%. Investigator Global Assessment ratings showed improvement by Week 4 and the

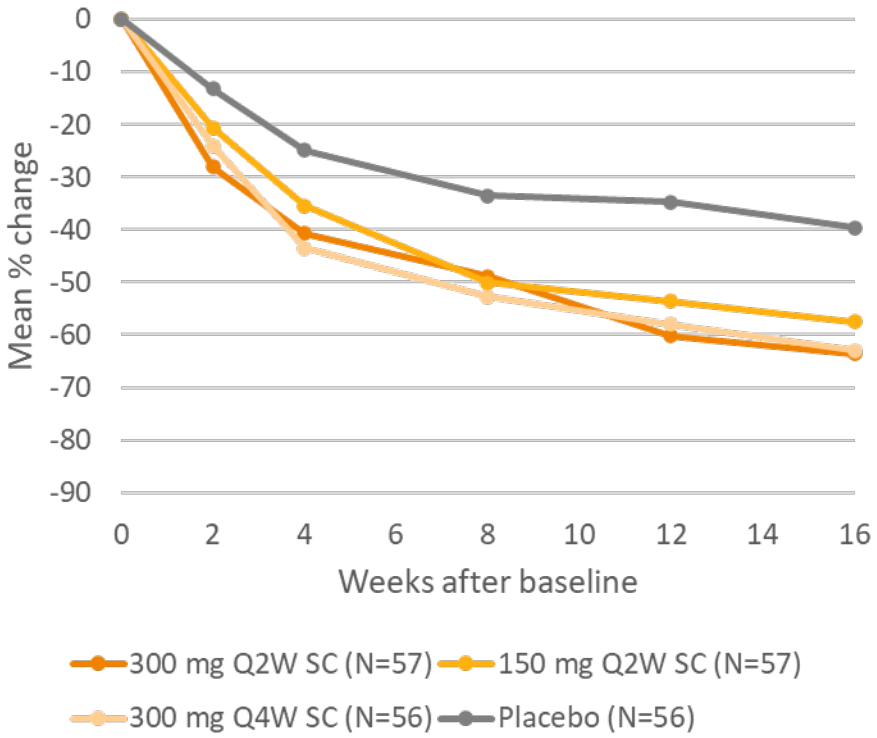
proportion of IGA responders (IGA 0/1 and ≥2 pt improvement) continued to increase to Week 16 (21.1%, 28.1%, 25.0% vs 12.5%, respectively)

Rapid improvements in efficacy were also observed in patients in China (N=32). These patients had greater improvements across 16 weeks of treatment with CBP-201 vs placebo, no CBP-201 discontinuations, and higher baseline EASI (median 26.9 vs 21.2) and BSA involvement (median 42.5% vs 35.1%) than the overall population. In China, at Week 16, mean EASI decreased by -83.7%, -59.4%, and -75.1% vs -32.5%, and mean BSA involvement decreased by -77.6%, -53.4%, and -71.5% vs -21.4%.

Conclusion: In patients with moderate-to-severe AD, rapid and clinically meaningful improvements in investigator-assessed symptoms occurred as early as the first assessment (Week 2), with further improvements observed across 16 weeks of treatment with CBP-201. These reductions in investigator-assessed AD severity are mirrored by improvements in patient-reported outcomes (see Silverberg et al, EADV 2022) and are compatible with previously reported investigator-assessed findings in this trial, including reductions in the primary endpoint (EASI at Week 16). These data also demonstrate the possibility of a reliably efficacious 2- and 4-week dosing option with CBP-201. The current findings support further investigation of CBP-201 300mg Q2W and Q4W in Phase 3 trials.

Efficacy outcomes in the overall population (LOCF analyses)

Eczema Area and Severity Index (EASI)



At Week 16:

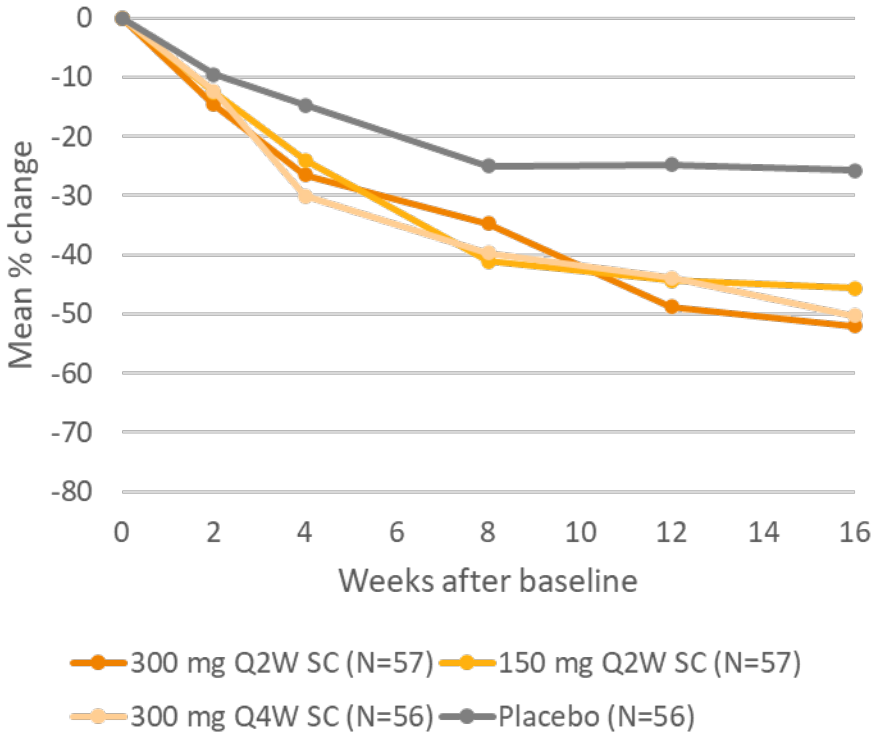
-39.7%

-57.6%

-63.0%

-63.6%

Percent Body Surface Area (BSA)



At Week 16:

-25.7%

-45.7%

-50.3%

-52.0%