This Phase 2b trial (WW001) assessed three efficacy and safety in AD, with more convenient Early phase trial data suggest the potential for CBP-201 is a novel monoclonal antibody that binds to a region of IL-4Rα. Atopic dermatitis (AD) is a chronic inflammatory disease characterized by intense pruritus and recurrent exacerbations. CBP-201 is a novel monoclonal antibody that binds to a region of IL-4Rα.

The primary endpoint was percent EASI change from baseline at Week 16. Secondary endpoints included proportion of patients with IGA 0 or 1 and a change from baseline in PP-NRS at Week 16. The primary and key secondary endpoints were analyzed using the Clopper-Pearson method in the FAS; for responder endpoints, missing values were imputed by last observation carried forward (LOCF).

CBP-201 300 mg efficacy responses were generally numerically greater than with 150 mg Q2W. All doses of CBP-201 met the primary endpoint (LS mean percent change in EASI at Week 16, from baseline, vs placebo), with greater reductions in the 300 mg Q2W and Q4W groups. These results support further investigation in Phase 3 trials of CBP-201 300 mg in moderate-to-severe AD that take into consideration how differences in trial design and the patient populations recruited may impact efficacy and safety outcomes.

For adverse events of special interest, CBP-201 had low rates of injection site reactions, herpes virus infections and conjunctivitis. CBP-201 and placebo had similar incidences of TEAEs, serious TEAEs, and TEAEs leading to discontinuation (Table 2).

Efficacy
- All doses of CBP-201 met the primary endpoint (a mean percent change in EASI of ≥10 at Week 16, from baseline, vs placebo), with greater reductions in the 300 mg Q2W and Q4W groups. These results support further investigation in Phase 3 trials of CBP-201 300 mg in moderate-to-severe AD that take into consideration how differences in trial design and the patient populations recruited may impact efficacy and safety outcomes.

Safety
- For adverse events of special interest, CBP-201 had low rates of injection site reactions, herpes virus infections and conjunctivitis.

Efficacy
- All doses of CBP-201 met the primary endpoint (a mean percent change in EASI of ≥10 at Week 16, from baseline, vs placebo), with greater reductions in the 300 mg Q2W and Q4W groups. These results support further investigation in Phase 3 trials of CBP-201 300 mg in moderate-to-severe AD that take into consideration how differences in trial design and the patient populations recruited may impact efficacy and safety outcomes.

Methodology
- The primary endpoint was percent change in EASI from baseline to Week 16.
- Secondary endpoints included proportion of patients with a change in IGA of −1 or ≥1, change in PP-NRS at Week 16, and proportion of patients achieving ACRPs at Week 16 (vs placebo).
- All doses of CBP-201 met the primary endpoint (LS mean percent change in EASI at Week 16, from baseline, vs placebo), with greater reductions in the 300 mg Q2W and Q4W groups. These results support further investigation in Phase 3 trials of CBP-201 300 mg in moderate-to-severe AD that take into consideration how differences in trial design and the patient populations recruited may impact efficacy and safety outcomes.

Results
- Baseline characteristics were generally well balanced across the treatment arms.
- Key inclusion and exclusion criteria:
  - Moderate-to-severe AD (IQA 3–5), age ≥1 year, body surface area (BSA) ≥80% involvement, and ≥16 weeks of moderate-to-severe AD
  - BMI ≥18 and ≤32 kg/m²
  - Median EASI 30–75
  - Disease duration ≥1 year
  - Male or female
  - Not pregnant, breastfeeding, or planning to become pregnant

- Table 2: Demographics of all participants

- Table 3: Demographics of all participants

- Figure 1: Design of CBP-201-WW001 Phase 2b trial

To evaluate the safety and tolerability of CBP-201 in AD, a randomized, double-blind, placebo-controlled, international trial (NCT04444752) comprised 16-week treatment and 8-week follow-up periods for 226 patients with moderate-to-severe AD. Baseline characteristics were generally well balanced across the treatment arms. Baseline characteristics were generally well balanced across the treatment arms.