Phase 3 trial demonstrates superior patient treatment convenience of MC2-01 calcipotriene plus betamethasone dipropionate cream compared to current topical suspension

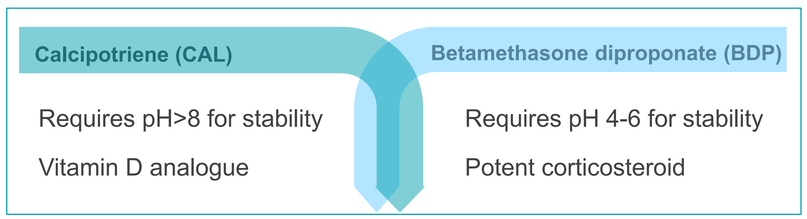
Morten Præstegaard[1], Birgitte Vestbjerg[1], Johan Selmer[1], Tove Holm-Larsen[2]

[1]MC2 Therapeutics, Hørsholm, Denmark; [2]Pharma Evidence, Farum, Denmark

INTRODUCTION:

PAD™ Technology has for the first time enabled formulation of MC2-01 cream is a first aqueous topical treatment of psoriasis containing the active ingredients calcipotriene and betamethasone dipropionate (0.005% / 0.064% w/w, CAL/BDP). MC2-01 cream is based on PAD™ Technology and designed for high penetration of the actives combined with excellent cosmetic elegance. Patient convenience data from a phase 3 trial is presented comparing MC2-01 cream to CAL/BDP topical suspension ("CAL/BDP TS") in adults with mild to moderate psoriasis.

Figure 1: Rationale for MC2-01 cream



- **Dual additive efficacy** of CAL and BDP
- **Improved safety** profile compared to the individual actives alone
  - BDP counteracts potential skin irritation of CAL
  - CAL mitigates potential skin atrophogenic effect of BDP
- **PAD™ Technology uniquely enables a stable combination of CAL and BDP in an elegant and fast absorbing aqueous cream**

Methods:

The Phase 3, randomized, multicenter, investigator-blind, parallel-group trial evaluated the efficacy, safety and convenience of MC2-01 cream compared to MC2-01 vehicle and the CAL/BDP TS (sourced as Taclonex® Topical Suspension) in adult patients with psoriasis vulgaris on the body. The trial enrolled 796 patients at 55 clinical sites across the United States: MC2-01 cream (n=343), CAL/BDP TS (n=338), MC2-01 vehicle (n=115). Patients applied trial medication once daily for eight weeks. The primary objective was to demonstrate non-inferiority of MC2-01 cream to CAL/BDP TS on PGA treatment success at Week 8. A novel patient treatment convenience scale (PTCS), currently being validated, was administered at Week 1, Week 4 and Week 8 to evaluate patient acceptance of the topical formulations (Fig. 5). The PTCS accumulates scores of five simple questions rated on an 10-point numeric rating scale with a high score indicating high convenience. An extra question evaluated overall satisfaction of the medical treatment. Superiority of PTCS at Week 8 comparing MC2-01 cream to CAL/BDP TS was evaluated as a secondary endpoint.

EFFICACY RESULTS:

The phase 3 trial met its primary objective of treatment success, and data further showed superiority of MC2-01 cream versus CAL/BDP TS at Week 8 (MC2-01 cream 40.1% vs. CAL/BDP TS 24.0%, p<0.0001) (Fig. 3). The secondary endpoint assessing patient treatment convenience (PTCS) at Week 8 demonstrated superiority of MC2-01 cream compared to CAL/BDP TS (41.5 vs. 37.5, p<0.0001) (Fig. 4).

Figure 2: Phase 3 trial design

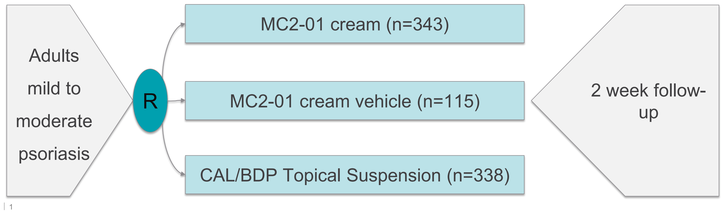


Fig.3: Primary efficacy variable: % PGA Treatment Success

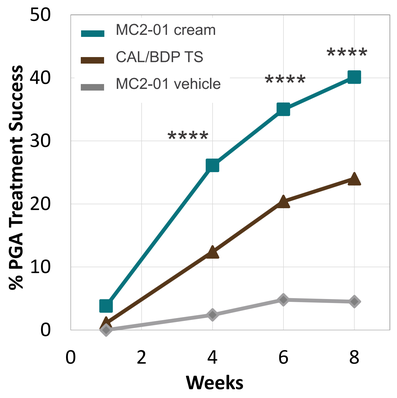
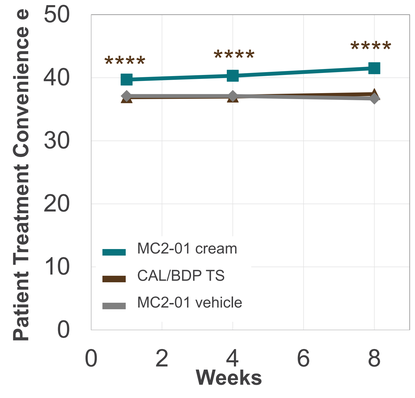
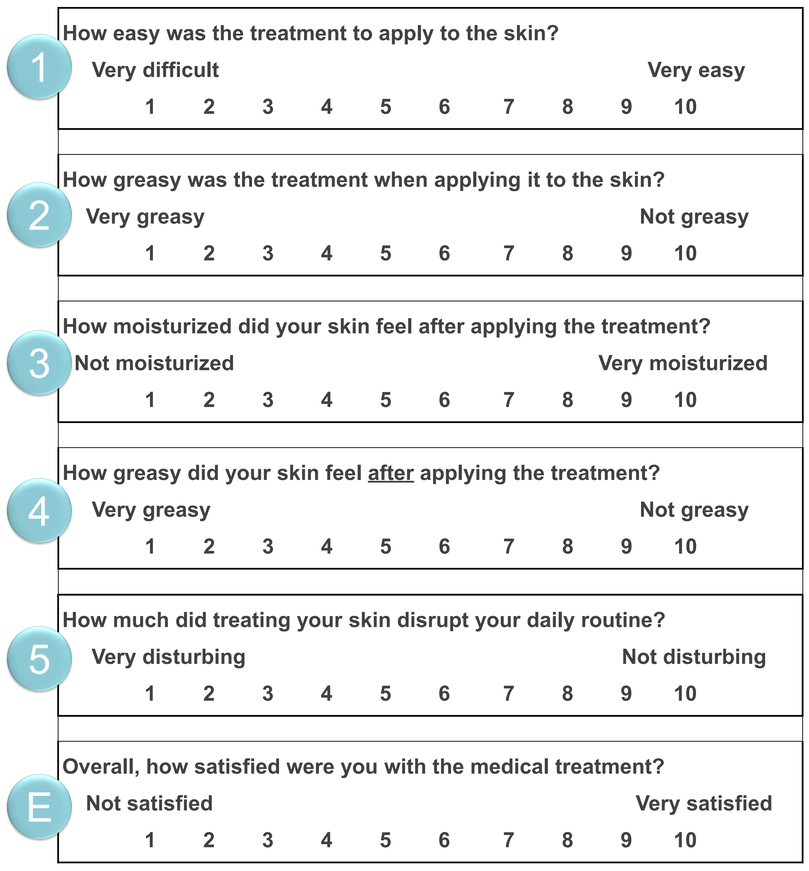


Fig.4: Secondary PRO variable: Patient Treatment Convenience



**** $p < 0.0001$ (MC2-01 cream vs. CAL/BDP TS)

Figure 5: Patient Treatment Convenience Scale (PTCS)

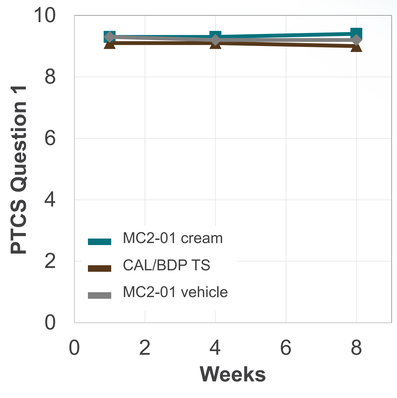


Further evaluation of MC2-01 cream treatment convenience at Week 1 (39.7 vs. 36.9, p<0.0001) and Week 4 (40.2 vs. 37.1, p<0.0001) confirmed superiority compared to CAL/BDP TS throughout treatment. Analysis of single questions clarified that the highest preference for MC2-01 cream versus CAL/BDP TS arose in questions "how greasy was the treatment when applying it to the skin" and "how greasy did your skin feel after applying the treatment", showing that lower greasiness is a key differentiating feature of MC2-01 cream compared to the topical suspension (Fig. 6). The extra question evaluating overall satisfaction with treatment followed the trend of other efficacy variables in the trial.

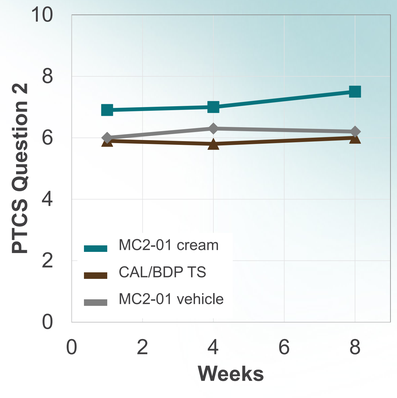
The safety profile of MC2-01 cream was similar to that known for CAL/BDP products.

Figure 6: PTCS individual questions

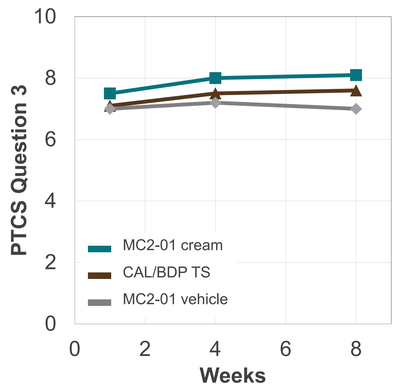
1) How easy was the treatment to apply to the skin?



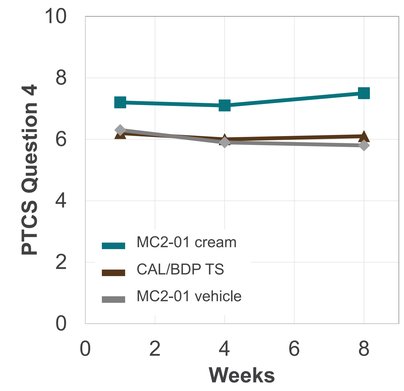
2) How greasy was the treatment when applying it to the skin?



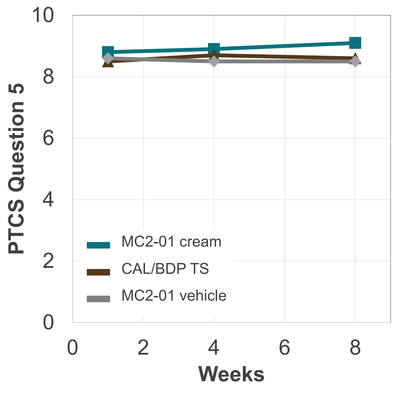
3) How moisturized did your skin feel after applying the treatment?



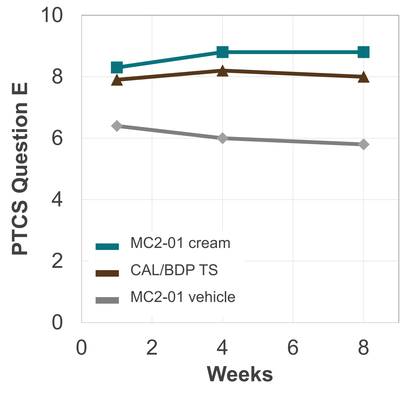
4) How greasy did your skin feel after applying the treatment?



5) How much did treating your skin disrupt your daily routine?



E) Overall, how satisfied were you with the medical treatment?



CONCLUSIONS

The phase 3 trial showed that MC2-01 cream has an improved overall efficacy compared to the current CAL/BDP TS. Superior patient convenience of MC2-01 cream enabled by the PAD™ Technology, including its lower greasiness, may increase treatment compliance among psoriasis patients, and positively impact real-life treatment outcomes even further.

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