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

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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.

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 Taclox® 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 a 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).

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.

INTRODUCTION:
PAD™ Technology uniquely enables formulation of MC2-01 cream in adults with mild to moderate psoriasis. Patient convenience data from a Phase 3 trial evaluated the efficacy, safety and convenience of MC2-01 cream compared to MC2-01 vehicle and the CAL/BDP TS (41.5 vs. 37.5, p<0.0001) (Fig. 4). The secondary endpoint assessing patient treatment convenience at Week 8 (MC2-01 cream 40.1% vs. CAL/BDP TS 24.0%, p<0.0001) (Fig. 3). 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, evaluated overall satisfaction of the medical treatment. Superiority of MC2-01 cream versus CAL/BDP TS on PGA treatment success at Week 8 (MC2-01 cream 40.1% vs. CAL/BDP TS 24.0%, p<0.0001) (Fig. 4).

Figure 2: Phase 3 trial design

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 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.