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 ORIGINAL ARTICLE

A Phase 3, Randomized Trial Demonstrating the Improved Efficacy and Patient Acceptability of Fixed Dose Calcipotriene and Betamethasone Dipropionate Cream

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ABSTRACT

Background: The fixed dose combination of calcipotriene and betamethasone dipropionate (CAL/BDP) is a well-established, efficacious, and safe topical treatment of psoriasis.

Method: A Phase 3, multicenter, randomized, investigator-blind, active, and vehicle-controlled trial enrolling 796 patients with moderate to severe psoriasis according to the Physician Global Assessment (PGA) scale. Products were applied once daily for 8 weeks.

Results: The proportion of patients achieving PGA treatment success after 8 weeks was statistically significantly greater for CAL/BDP cream (37.4%) compared to CAL/BDP TS (22.8%, $P<0.0001$), and vehicle (3.7%, $P<0.0001$). A similar statistically significant difference in favor of CAL/BDP cream at week 8 was demonstrated for the percentage change in mPASI from baseline and the proportion of patients obtaining mPASI75. Patient reported treatment convenience for CAL/BDP cream was rated superior to CAL/BDP TS. Safety assessments during the trial demonstrated that CAL/BDP cream was well-tolerated with no adverse reactions with a frequency greater than 1%.

Conclusion: CAL/BDP cream is a novel topical treatment of psoriasis, which in a single product, offers a unique combination of high efficacy combined with favorable safety and excellent treatment convenience. For these reasons, CAL/BDP cream offers a distinctive advantage for the topical treatment of plaque psoriasis.

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INTRODUCTION

Psoriasis is an inflammatory skin disease that has a profound influence on all aspects of quality of life, including physical, psychologic, social, sexual, and occupational elements. Most psoriasis patients are candidates for topical treatments, and the fixed dose combination of calcipotriene (CAL) and betamethasone dipropionate (BDP) is a well established treatment option based on strong scientific rationale for the single agents having complementary efficacy and safety.

The CAL/BDP combination is recommended both by European guidelines[1-3] as a first line treatment of mild to moderate plaque psoriasis and is also recommended by the Canadian Dermatology Association,[4] and the American Academy of Dermatology.[5]

The currently marketed 0.005 w/w% CAL and 0.064 w/w% BDP fixed dose combinations are non-aqueous formulations containing petrolatum or mineral oil as the predominant excipient. Conversely, the CAL/BDP cream is an easily spreadable cream based on the proprietary PAD™ Technology (MC2Therapeutics), which has enabled development of a water-containing formulation of CAL and BDP, despite their known pH-related instability when combined in the presence of water.[6]

Treatment non-adherence is a well-known problem in dermatology and an important reason for treatment failure.[7,8] In a European survey of non-adherence of topical treatment in psoriasis, 73% of the patients did not adhere to the prescribed treatment regime. The principal reason for non-adherence was the greasiness of the product.[9] Other studies have also demonstrated that adherence is affected by treatments which are greasy or oily, stain clothes, are difficult to apply, or dosed more than once daily.[10,11]

CAL/BDP cream has the in-use characteristics of an easily spreadable cream, which absorbs rapidly and completely into the skin leaving no sticky feeling behind. It is anticipated that these qualities will result in increased patient adherence and consequently, improved real-world treatment outcomes.[12] The