Long-term proactive management of psoriasis vulgaris with fixed-dose combination of calcipotriene 0.005% and betamethasone dipropionate 0.064% foam: results of a Phase III randomized controlled trial

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Introduction

- Topical therapies are considered first-line treatment for psoriasis,¹ however maintaining long-term disease control is a challenge, with many patients untreated or undertreated.² Current topical psoriasis treatment relies on a reactive approach to disease flares, as opposed to a more long-term proactive approach.³
- Data supporting the efficacy and safety of calcipotriene 0.005% and betamethasone dipropionate 0.064% (Cal/BD) foam approved as a reactive treatment are available from trials of 4- and 12-week duration in patients with psoriasis vulgaris (plaque psoriasis).⁴ ⁵ ⁶ ⁷
- Here, we report the efficacy of Cal/BD foam in long-term proactive management of psoriasis over 52 weeks (NCT00899692). Data from the open-label lead-in phase of this trial are presented in poster #11630.

Materials and Methods

- Eligible patients for this Phase III, multicentre trial received once-daily Cal/BD foam during the 4-week open-label lead-in phase (Figure 1).
  - Patients with trunk and/or limb psoriasis, involving 2-30% of body surface area (BSA): physician’s global assessment (PGA) of disease severity ≤ mild; modified psoriasis area and severity index (m-PASI) ≤ 32.
  - Patients achieving success at the end of the open-label lead-in phase (PGA score ‘clear’ or almost ‘clear’ (PGA <2) with ≥2-grade improvement from baseline of the open-label lead-in phase) were randomized 1:1 to twice-weekly Cal/BD foam or vehicle foam for 52 weeks (Figure 1).

Double-blind treatment during the maintenance phase

- ‘Proactive’ management was treatment with Cal/BD foam twice-weekly for 52 weeks when in remission.
- ‘Reactive’ management was treatment with vehicle foam twice-weekly for 52 weeks when in remission.
- Relapse: PGA ≥2 [either previously treated and/or new skin area)] (flare medication as separate flare bottles) was Cal/BD foam once-daily for 4 weeks for both the proactive and reactive management groups (Figure 1).

Primary objective and endpoints

- To evaluate the efficacy of a twice-weekly proactive maintenance regimen with Cal/BD foam compared with reactive management with vehicle foam in the prevention of relapse in patients with psoriasis.
  - Time to first relapse (defined as a PGA score of at least ‘mild’ [PGA<2]).

Trial design and treatments

Figure 1. Trial design

- Study design: Parallel, multicentre, double-blind, active-controlled, randomized trial.
- Treatment: Cal/BD foam 0.005% calcipotriene plus 0.064% betamethasone dipropionate (Cal/BD) foam or vehicle foam (Vehicle) twice weekly for 52 weeks (Figure 1).
- Randomization: 1:1 randomisation to Cal/BD foam or vehicle foam for 52 weeks (Figure 1).

Secondary objective and endpoints

- To evaluate the long-term efficacy (up to 52 weeks) of proactive maintenance treatment compared with reactive management in patients with psoriasis.
  - Number of relapses.
  - Proportion of days in remission (PGA<2).

Safety objective

- Safety endpoints, objectives, and data are presented in poster #12797.

Results

Patient population

- 545 patients were randomized (safety analysis set [SAS]) 119 patients had missing data).
  - 426 patients completed the trial (safety analysis set [SAS]: n=426).

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Table 1. Time to first relapse

<table>
<thead>
<tr>
<th>Proactive (N=256)</th>
<th>Reactive (N=255)</th>
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<tr>
<td>Median time to first relapse*</td>
<td>55 days</td>
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*Number of days from the randomization of patients who had experienced their first relapse.

Conclusions

- Proactive management with Cal/BD foam was superior in prolonging time to first relapse, reducing number of relapses and increasing days in remission versus vehicle-controlled reactive management.
- The results of this trial are promising. They are the first to demonstrate that proactive management with fixed-dose Cal/BD foam could offer improved long-term control of psoriasis over conventional reactive treatment.

References


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