Efficacy and Safety of Apremilast in Patients With Moderate to Severe Plaque Psoriasis of the Scalp: Results of a Phase 3, Multicenter, Randomized, Placebo-Controlled, Double-Blind Study

INTRODUCTION

• Psoriasis is a chronic, inflammatory skin disorder that requires long-term treatment and continued monitoring (monitoring).
• Many patients with psoriasis report that scalp and facial symptoms are difficult to treat and may be associated with a negative impact on quality of life.
• Topical therapies can be difficult to apply to the scalp area and may feel greasy on the hair.

METHODS

Primary Objective:
- To evaluate the efficacy of Apremilast (APR) vs. placebo (PBO) in patients with moderate to severe plaque psoriasis of the scalp.

Secondary Objectives:
- To evaluate the safety and tolerability of APR in patients with moderate to severe plaque psoriasis of the scalp.

Key Inclusion Criteria:
- Presence of plaque psoriasis in the scalp
- Presence of a Physician Global Assessment (PGA) of 3 or greater

Key Exclusion Criteria:
- History of psoriatic arthritis
- Use of systemic corticosteroids or immunomodulators within the past 4 weeks

Study Design:
- Open-label phase (N=200)
- Placebo-controlled phase (N=200)

RESULTS

Patient Population:
- N=401 patients randomized to APR (n=201) or PBO (n=200)
- Mean age: 51.4 years
- Mean PGA score at baseline: 4.7

Table 1: Demographics and Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>APR (n=201)</th>
<th>PBO (n=200)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, Mean (range)</td>
<td>51.4 (18-80)</td>
<td>50.2 (18-80)</td>
</tr>
<tr>
<td>Sex, Female (%)</td>
<td>54.4</td>
<td>51.5</td>
</tr>
<tr>
<td>Baseline PGA, Mean (SD)</td>
<td>4.7 (1.2)</td>
<td>4.7 (1.2)</td>
</tr>
</tbody>
</table>

Scalp and Whole Body Itch
- Itch was measured using a numerical rating scale (NRS) of 0 (no itch) to 10 (worst imaginable itch).

Table 2: Overview of Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>APR (n=201)</th>
<th>PBO (n=200)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (%)</td>
<td>40.3</td>
<td>13.7</td>
</tr>
<tr>
<td>Most common adverse events</td>
<td>38.8</td>
<td>10.8</td>
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</table>

CONCLUSIONS

- APR was efficacious and safe in the treatment of scalp psoriasis.
- APR demonstrated statistically significant improvements in itch and quality of life measures compared to PBO.
- APR was well tolerated with a similar safety profile to PBO.

REFERENCES


CORRESPONDENCE

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DISCLOSURES

- All authors disclose relationships with the following companies: AbbVie, Amgen, Celgene Corporation, Eli Lilly, Janssen, Merck, Novartis, and Pfizer.
- The authors acknowledge the following financial support for this study: Celgene Corporation, Janssen, Lilly, and Novartis.
- The authors received editorial support from Peloton Advantage, LLC.
- The authors acknowledge financial support from Celgene Corporation.
- The authors directed and are fully responsible for all content and editorial decisions.

ACKNOWLEDGMENTS

The authors acknowledge support for this study from Celgene Corporation. The authors received no external financial support in the preparation of this document.

Presented at: Winter Clinical Dermatology Conference–Hawaii; January 18–23, 2019; Koloa, HI.