INTRODUCTION

- AD is a chronic inflammatory skin disease; patients with AD are at higher risk for other atopic comorbidities, such as food allergies.
- The prevalence of food allergy in AD ranges from 20% to 60% in this population.
- Although it is not clear whether the presence of food allergy makes AD more difficult to treat, there is an association between ingestion of food that triggers an allergic reaction and AD exacerbation.
- Crisaborole, 2%, is an anti-inflammatory nonsteroidal PDE4A inhibitor for the treatment of patients aged 13 months (22 years of age outside the United States) with mild-to-moderate AD.
- Initial approval was based on the results from 2 identically designed, vehicle-controlled, phase 3 clinical studies: CORE 1 (NCT02118768) and CORE 2 (NCT02118769).

RESULTS

Patients

- In the pooled study population, 1,016 patients received crisaborole 50% received vehicle.
- Among them, 251 reported a past medical history of food allergy and 127 did not have a past medical history of food allergy.

Baseline demographics were generally similar between treatment arms and among those who did and those who did not have food allergies.

Regardless of baseline characteristics, for those with a past medical history of food allergies, a relatively greater proportion (1) used systemic corticosteroids previously, (2) used antihistamines concurrently, and (3) had moderate or severe ISGA at baseline, and (4) had greater ISGA involvement with AD lesions (Table 1).

Table 1. Baseline Demographics and Disease Characteristics in Patients With and Without Food Allergies

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Vehicle (n=860)</th>
<th>Crisaborole (n=864)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>71.1 (108)</td>
<td>71.6 (108)</td>
<td>0.75</td>
</tr>
<tr>
<td>Female, % (n)</td>
<td>59.6 (515)</td>
<td>60.3 (520)</td>
<td>0.83</td>
</tr>
<tr>
<td>Concurrent use of topical agents</td>
<td>21.2 (212)</td>
<td>22.0 (218)</td>
<td>0.71</td>
</tr>
<tr>
<td>Concurrent use of antibiotics</td>
<td>2.3 (23)</td>
<td>2.7 (24)</td>
<td>0.57</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>10 (6, 15)</td>
<td>10 (6, 15)</td>
<td>0.36</td>
</tr>
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</table>

Objectives and Assessments

- The ISGA, a 5-point physician-reported scale of AD severity, was assessed at baseline and weekly thereafter.
- Pruritus severity was assessed using the SPS, a validated patient-reported 4-point rating scale, and reported twice daily (morning and evening) via electronic diary.

Efficacy outcomes were

- Patients who achieved ISGA success (defined as an ISGA of clear or almost clear [0] at 12-week improvement from baseline) at day 29.
- Patients who achieved ISGA success at day 29 (clear or almost clear [0] at 12-week improvement from baseline) at day 29.
- Patients who experienced improvement in SPS score (defined as a weekly average SPS score ≥1 point with ≥1-point improvement from baseline at each week).

Safety

- Outcomes included ITAEs (all cause and treatment-related), serious AEs, and AEs of special interest (eg, anaphylaxis).

Efficacy

- The proportion of patients who achieved ISGA success at day 29 was significantly greater in the crisaborole treatment group than in the group treated with vehicle, regardless of past medical history of food allergies (Figure 1).
- Similarly, in patients with or without food allergies, a significantly greater proportion of crisaborole-treated patients achieved ISGA clear or almost clear at day 29 than those given vehicle (Figure 2).
- At week 4, a numerically greater improvement in SPS score was observed in patients with or without food allergies in the crisaborole group than in the vehicle group achieved improvement in SPS score; however, it was only statistically significant in the patients without the history of food allergies (Figure 3).

Safety

- The safety profile was generally similar between patients with food allergies and those without food allergies.
- Among patients with food allergies, 61 crisaborole-treated patients (40.1%) and 40 vehicle-treated patients (40.8%) experienced at least one TEAE.
- Among crisaborole-treated patients with food allergies, 22 (14.5%) experienced at least one TEAE compared with 7 (5.0%) experienced a serious TEAE; the serious TEAE was not considered related to treatment.
- No anaphylaxis was reported in any group.

Table 2. Most Common (>2%) Patient TEAEs (all cause) in Patients With and Without Food Allergies

<table>
<thead>
<tr>
<th>TEAE</th>
<th>Vehicle (n=860)</th>
<th>Crisaborole (n=864)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper respiratory tract infection</td>
<td>1.0 (1)</td>
<td>1.2 (1)</td>
<td>0.92</td>
</tr>
<tr>
<td>Staphylococcal skin infection</td>
<td>0.2 (1)</td>
<td>0.2 (1)</td>
<td>0.84</td>
</tr>
<tr>
<td>Rhinopharyngitis</td>
<td>1.0 (1)</td>
<td>0.2 (1)</td>
<td>0.51</td>
</tr>
</tbody>
</table>

CONCLUSIONS

- Regardless of whether patients have food allergies, crisaborole is effective in treating mild-to-moderate symptoms of AD.
- The safety profile was generally similar between patients with food allergies and those without food allergies; no new safety signals were observed.
- Crisaborole should be considered for management of AD in patients with or without a history of food allergies.