Onset of Action With Glycopyrronium Cloth in the Treatment of Primary Axillary Hyperhidrosis

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INTRODUCTION

Axillary hyperhidrosis (AH) is a common benign condition characterized by excessive perspiration that causes significant patient distress. Various non-surgical and surgical treatments have been utilized, but few improve clinical outcomes or are associated with long-term efficacy.

The efficacy and safety of GT in the treatment of AH was demonstrated in two double-blind, vehicle (VEH)-controlled Phase 3 trials (ATMOS-1 and ATMOS-2) with open-label extension (OLE).

OBJECTIVE

The objective of the study was to evaluate the onset of action in the Phase 3 trials, examining results from the first week of treatment.

METHODS

ATMOS-1 and ATMOS-2 Study Design

- Patients were randomized 1:1 to GT or VEH on Day 0.
- A steady-state period of approximately 4 weeks (Period 1) was followed by 4 weeks of treatment (Period 2).
- A 4-week OLE period was conducted following Period 2.

RESULTS

Deposition, Derangements, and Baseline Disease Characteristics

- Patient demographics and baseline disease characteristics were similar across treatment arms and across studies (Table 1).

Efficacy and Safety Assessments

- Comparative analyses of continuous data from Baseline and treatment period 1 showed improvement in median reductions in sweating severity.

Efficacy: Co-primary Endpoints

- A markedly greater proportion of GT patients achieved ≥4-point ASDD/ASDD-C Item 2 improvement from Baseline compared to VEH patients on both co-primary endpoints (Δ≥2-grade reduction from Baseline).
- For the analyses evaluating daily ASDD/ASDD-C Item 2 responder rate over the first 7 days:

Efficacy: Daily and Weekly Findings (ASDD Items 3 and 4)

- A significant advantage for GT over VEH was observed on both co-primary endpoints (Δ≥4-point improvement from Baseline).

Medication Exposures

- GT was well-tolerated; adverse events were mild to moderate in severity, and transiently led to discontinuation (Table 2).

CONCLUSIONS

- GT demonstrated early onset of efficacy, with >90% of patients achieving ≥4-point ASDD/ASDD-C Item 2 improvement from Baseline in the first week of treatment.

REFERENCES


ACKNOWLEDGMENTS

- Portions of this study were presented at the 37th Fall Clinical Dermatology Conference, Las Vegas, NV; October 18-21, 2018.

DISCLOSURES

- This work was supported by Allergan plc. The datasets and study material are publicly available on ClinicalTrials.gov with identification numbers NCT02559521 and NCT02559522.

Table 2. Safety Overview (Safety Population)

<table>
<thead>
<tr>
<th>TEAE</th>
<th>GT (n=447)</th>
<th>VEH (n=234)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinued</td>
<td>14 (3.1%)</td>
<td>2 (0.8%)</td>
</tr>
<tr>
<td>Protocol violation</td>
<td>10 (2.2%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Withdrew consent</td>
<td>3 (0.7%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Adverse event</td>
<td>75 (16.8%)</td>
<td>26 (11.1%)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (1.1%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

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