Burden of Axillary Hyperhidrosis Using a Patient-Reported Outcome Measure to Assess Impact on Activities and Botherednesses

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INTRODUCTION

Axillary hyperhidrosis, which is estimated to affect 4.8% of the US population or approximately 15.1 million people, is associated with considerable impairment in work productivity, social activities, emotional well-being, and personal relationships.1

• Topical glycopyrronium is the only FDA-approved treatment for axillary hyperhidrosis.
• In a previous report, from a phase 3 clinical trial (ATMOS-1 and -2), the treatment of primary axillary hyperhidrosis with glycopyrronium tosylate (GT; formerly DRM-04) resulted in a significant improvement in weekly impact and bother, as defined by scores of 3 or 4 on ASDD items 2 and 3 or 4 on HDSS items 3 and 4, respectively.

METHODS

ATMOS-1 and ATMOS-2 Study Design

• ATMOS-1 (NCT02352031; site in the US and Germany) and ATMOS-2 (NCT03333294; US site only) were parallel-group, 4-week, double-blind, phase 3 clinical trials in which patients with primary axillary hyperhidrosis were randomized (2:1) to GT or vehicle (Figure 1).

• Patients were excluded for history of a condition that could cause secondary hyperhidrosis or prior surgical procedure or treatment with a medical device for axillary hyperhidrosis; treatment with topical products within 2 weeks or treatment with botulinum toxin for axillary hyperhidrosis within 1 year; axillary use of nonprescription antiperspirants within 1 week or prescription antiperspirant within 2 weeks; new or modified psychotherapeutic medication regimen within 2 weeks; treatment with medications having systemic anticholinergic activity; contraindication of alpha-2 adrenergic agonist, or beta-blockers within 4 weeks unless dose had been stable for ≥4 months and was not expected to change; and/or conditions that could be exacerbated by study medication.

RESULTS

- A total of 697 patients were randomized and asked to complete items assessing the impact of and bother from sweating (items 3 and 4, respectively) and the Weekly Impact scale (Table 2).
- Demographics and Baseline disease characteristics were similar between studies (Table 2).

Table 2. Baseline Demographic and Disease Characteristics (ITT Populations)

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Baseline</th>
<th>GT</th>
<th>Vehicle</th>
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</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>42.0 ± 11.0</td>
<td>42.5 ± 11.3</td>
<td>41.5 ± 11.0</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>257 (70.8)</td>
<td>255 (76.0)</td>
<td>202 (62.6)</td>
</tr>
<tr>
<td>Race (white)</td>
<td>515 (74.6)</td>
<td>511 (73.6)</td>
<td>433 (74.5)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.2 ± 5.5</td>
<td>26.5 ± 5.4</td>
<td>25.9 ± 5.3</td>
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</tbody>
</table>

- At Baseline in ATMOS-1 and ATMOS-2, the mean ± SD ASDD/ASDD-C axillary sweating severity item (item 3) scores were 7.2 ± 1.6 and 7.3 ± 1.6, respectively.
- In each trial, more than half of all patients reported weekly average scores ≥7 before randomization, indicating that patients considered their sweating to be moderate or severe at Baseline (Figure 2).
- 18.0% and 19.2% of patients rated the severity of their axillary sweating as ≥9 in ATMOS-1 and ATMOS-2, respectively, indicating severe axillary hyperhidrosis at Baseline (Figure 2).

CONCLUSIONS

- At Baseline, the majority of patients who were ≥16 years of age were bothered by their sweating and/or treatments they were using. A large proportion of patients were severely bothered by axillary sweating (scores ≥9), to the extent that they were more likely to feel less confident in themselves, more embarrassed by their sweating, and/or less confident or embarrassed by their sweating during an activity. At Baseline, more than 96% of patients reporting feeling embarrassed were bothered by their sweating.

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