INTRODUCTION

- Hyperhidrosis affects an estimated 6.8% of the US population or approximately 15 million people, and the impact of hyperhidrosis on quality of life is reported as comparable to, or greater than, weakness or pain.

- Topical anticholinergic therapy (GT) for primary axillary hyperhidrosis is a well-accepted treatment option, but whether the use of these drugs is associated with meaningful improvements in disease severity and reductions in sweat production has not been established.

METHODS

- Study Design:
  - ARIDO was a 44-week, open-label extension of ATMOS-1/ATMOS-2, a 24-week, double-blind, phase 3 clinical trials in which patients with primary axillary hyperhidrosis were randomized to GT (127.5 mg topical solution) or vehicle applied once daily to each axilla for 28 days.

- Patients who completed ATMOS-1/ATMOS-2 with ≤1 TEAEs of interest were eligible to continue in ARIDO and receive open-label GT for 44 weeks or until early termination (Figure 1).

- Eligible patients were ≥16 years of age and had primary axillary hyperhidrosis for at least 1 month, and had not received anticholinergic drugs, surgery, or botulinum toxin injections to the axilla within 1 year for hyperhidrosis; prior surgical procedure or treatment with a medical device for hyperhidrosis; previous or concurrent treatment with a medical device or a medication that could change hyperhidrosis. Patients were excluded for a history of any condition that could cause secondary hyperhidrosis, prior surgical procedure or treatment with a medical device for axillary hyperhidrosis, treatment with anticholinergics within 4 weeks or treatment with botulinum toxin within 1 year for axillary hyperhidrosis, use of prescription antiperspirants within 1 week or prescription antiperspirants within 2 weeks, or nonprescription antiperspirants within 1 month; history of alcohol or drug abuse; and history of congenital abnormalities or genetic disorders.

- All safety and efficacy analyses were performed on the Safety Population (patients receiving at least 1 dose of GT and having at least 1 post-Baseline assessment in ARIDO).

RESULTS

- The majority of patients (68.0%; N=435) completing ATMOS-1/ATMOS-2 (369 patients [84.8%] who completed ATMOS-1 and 196 [41.4%] who completed ATMOS-2) continued into ARIDO (Figure 2).

- Of the 329 patients enrolled in ARIDO, 319 (97.0%) were female (62.0%) and 232 (69.0%) and had a mean age of 33.4 years, and mean BMI of 27.7 kg/m².

Assessments

- Primary objective was long-term safety.

- Secondary objectives were:
  - Change from Baseline in ATMOS-1/ATMOS-2 and ARIDO in gravimetrically-measured average rate of sweat production from the left and right axillae, the left axilla, and the right axilla, respectively, at Baseline in ATMOS-1/ATMOS-2 and ARIDO.
  - Change from Baseline in ATMOS-1/ATMOS-2 and ARIDO in HDSS responder rate (≥2-grade improvement) at Wk 44 vs Wk 48 of GT treatment.

Efficacy Assessments

- Change from Baseline in ATMOS-1/ATMOS-2 and ARIDO in gravimetrically-measured average rate of sweat production at Wk 44 vs Wk 48 of GT treatment.

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Figure 1. Study Design

Figure 2. Patient Disposition

Figure 3A. Mean Sweat Production and HDSS Improvement From Baseline to Week 44/48 (Safety Population)

Figure 3B. Prespecified anticholinergic TEAEs of interest, n (%)

Table 1. Demographics and Baseline Disease Characteristics (Safety Population)

Table 2. Summary of Treatment-Emergent Adverse Events From Baseline to Week 45/48 (Safety Population)

Table 3. Summary of Frequently Reported TEAEs and TEAEs of Special Interest (Safety Population)

CONCLUSIONS

- Safety results were consistent with anticholinergic treatment and would be similar to those observed in prior GT studies if there were no new or unexpected findings.

- No new or unexpected TEAEs were reported or observed in any population.

- No new or unexpected 

- Effectiveness of GT treatment was maintained for 44 weeks, and GT treatment was generally well tolerated and demonstrated clinically meaningful improvements in disease severity and reductions in sweat production.

- Gravimetrically-measured average from the left and right axillae patients [65.4%] had received GT, and 195

- The majority of patients (86.6%; N=564) completing ATMOS-1/ATMOS-2 (369

- Large, randomized, double-blind, phase 3 clinical trials in which patients with primary axillary hyperhidrosis were randomized to GT (127.5 mg topical solution) or vehicle applied once daily to each axilla for 28 days.

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