Hyperhidrosis affects an estimated 4.8% of the US population, or approximately 15.3 million people, and the

INTRODUCTION

Primary axillary hyperhidrosis treated for at least 12 months

METHODS

Open-Label Study (ARIDO) Evaluating Long-Term Safety of Topical Glycopyrronium Tosylate (GT) in Patients With Primary Axillary Hyperhidrosis

RESULTS

CONCLUSIONS

A. Sweat Production

Efficacy Assessments

Attainment of 80% or greater reduction in axillary hyperhidrosis severity (HDSS) was assessed using a validated

Assessments

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

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

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

Baseline Disease Characteristics

For patients receiving ≥1 dose of GT and having ≥1 post-Baseline assessment on ARIDO

Grade 4

None

1 Grade

2 Grades

3 Grades

4 Grades

>4 to 8

>8 to 20

>20

Adverse Events

Week 44/ET

Mean CfB: -95.7 ± 140.8 mg/5 min

Grade 1

Grade 2

Grade 3

Grade 5

Mean of Percent Change from Baseline

Safety Assessments

Grade 3

Permission in ARIDO-2

Permission in ARIDO-1

Week 44/ET

Safety Assessments

Hyperhidrosis treated for at least 12 months

• Enter ARIDO (up to 48 weeks of GT)

• cdTEA (T or E) (Safety Populationb)

• Percent change from Baseline in ATMOS-1/ATMOS-2 in HDSS responder rate (≥2-grade improvement) at Week 44

• Percent change from Baseline in ATMOS-1/ATMOS-2 in gravimetrically-measured sweat production at Week 44

Deaths, n (%)

0 to 4

1 to 4

4 to 8

>8

• Percent change from Baseline in ATMOS-1/ATMOS-2 in mean percent change in HDSS after treatment

• Change from Baseline in ATMOS-1/ATMOS-2 for clinic-assessed hyperhidrosis severity (HDSS)

• Change from Baseline in ATMOS-1/ATMOS-2 for physician-assessed hyperhidrosis severity (HDSS)

• Change from Baseline in ATMOS-1/ATMOS-2 for patient-reported hyperhidrosis severity (HDSS)

• Change from Baseline in ATMOS-1/ATMOS-2 in HDSS responder rate (≥2-grade improvement) at Week 44

• Mean of Percent Change from Baseline

• Mean of Percent Change from Baseline

• Change from Baseline in ATMOS-1/ATMOS-2 in gravimetrically-measured sweat production at Week 44

• Percent change from Baseline in ATMOS-1/ATMOS-2 in gravimetrically-measured sweat production at Week 44

• Change from Baseline in ATMOS-1/ATMOS-2 for overall hyperhidrosis severity (HDSS)

• Change from Baseline in ATMOS-1/ATMOS-2 for physician-assessed hyperhidrosis severity (HDSS)

• Change from Baseline in ATMOS-1/ATMOS-2 for patient-reported hyperhidrosis severity (HDSS)

• Change from Baseline in ATMOS-1/ATMOS-2 for physician-assessed hyperhidrosis severity (HDSS)

• Change from Baseline in ATMOS-1/ATMOS-2 for overall hyperhidrosis severity (HDSS)

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