A 44-Week Open-Label Study Evaluating Safety and Efficacy of Topical Glycopyrronium Tosylate in Patients with Primary Axillary Hyperhidrosis

American Journal of Clinical Dermatology

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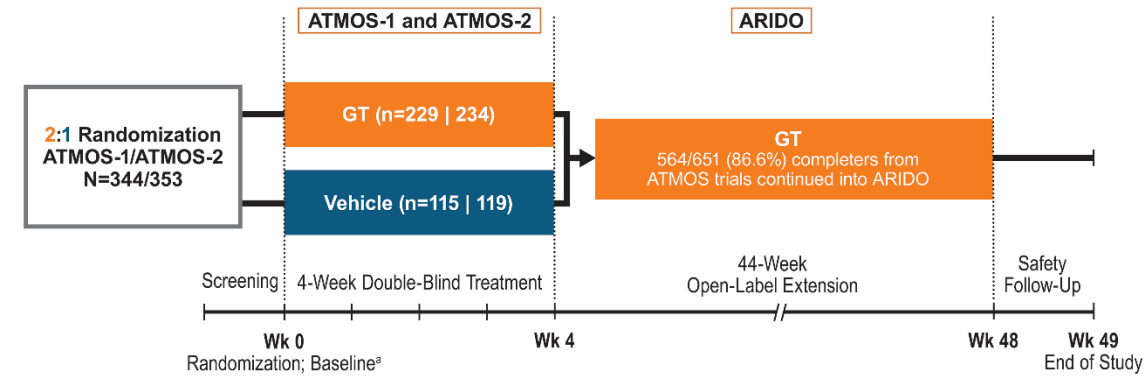
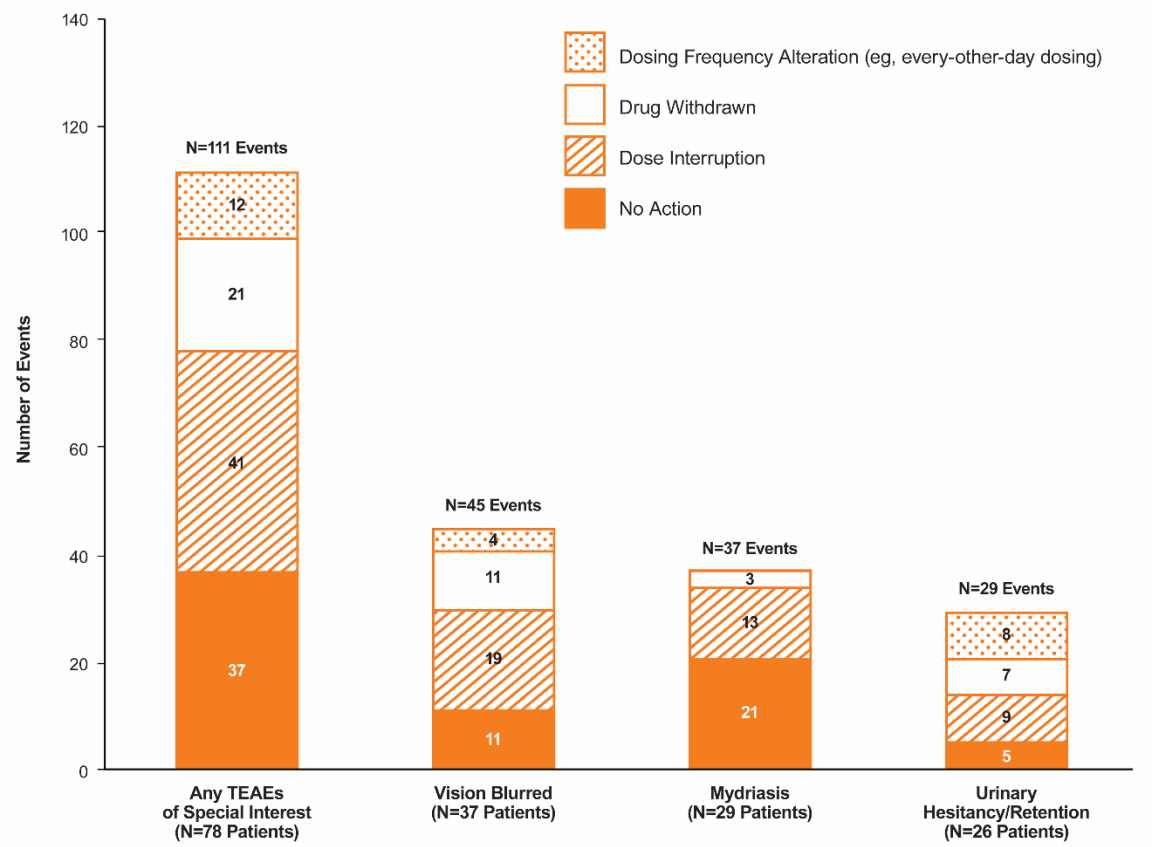


Supplemental Figure 1. Study Design. [a]For efficacy assessments, Baseline for the ARIDO open-label extension was Week 0 of the double-blind ATMOS-1/ATMOS-2 trials. GT, Glycopyrronium tosylate.



Supplemental Figure 2. Management of TEAEs of Special Interest in the Open-Label Trial. The MedDRA preferred terms that were pre-specified as TEAEs of special interest were vision blurred, mydriasis, pupils unequal, hypermetropia and the following terms for symptoms of urinary hesitancy/retention: nocturia, pollakiuria, urinary hesitation, urinary retention, urinary obstruction, and urine flow decreased. Though dry mouth is often associated with anticholinergic use, it was not designated as one of the pre-specified TEAEs of special interest and is not reflected in this figure. Patients may have had more than 1 TEAE of special interest. Safety outcomes from the first application of study drug in the open-label trial are reported. The safety population includes patients receiving ≥1 dose of GT and having ≥1 post-Baseline assessment in the open-label extension. TEAE, treatment-emergent adverse event.

Supplemental Table 1. Baseline Disease Characteristics (Day 1 of Open-Label Trial [Week 4 of Double-Blind Trials])

	GT→GT n=361	VEH→GT n=189	Total N=550
Sweat production (mg/5 min)			
Mean ± SD[a]	51.1 ± 90.0	85.1 ± 98.6	62.8 ± 94.3
Median	29.0	57.0	36.7
Min to max	0.5 to 1179	3.4 to 804.4	0.5 to 1179
HDSS, n (%)[b]			
Grade 1	149 (41.3)	26 (13.8)	175 (31.8)
Grade 2	172 (47.6)	83 (43.9)	255 (46.4)
Grade 3	30.0 (8.3)	59.0 (31.2)	89.0 (16.2)
Grade 4	10.0 (2.8)	21.0 (11.1)	31.0 (5.6)
DLQI, mean ± SD[c]	3.3 ± 4.3 [n=339]	6.1 ± 5.7 [n=173]	4.2 ± 5.0 [n=512]
CDLQI, mean ± SD[d]	1.6 ± 2.1 [n=21]	6.4 ± 7.3 [n=16]	3.7 ± 5.5 [n=37]

[a]Gravimetrically-measured average from the left and right axillae
[b]Total N=549; 1 patient entered ATMOS-2 with HDSS=2, which was a protocol violation
[c]Patients >16 years of age
[d]Patients ≤16 years of age

The safety population includes patients receiving ≥1 dose of GT and having ≥1 post-Baseline assessment in the open-label extension.

CDLQI, children's DLQI; DLQI, Dermatology Life Quality Index; GT, Glycopyrronium tosylate; GT→GT, patients assigned to GT in the double-blind trials who continued on GT in the open-label extension; HDSS, Hyperhidrosis Disease Severity Scale; SD, standard deviation; VEH, vehicle; VEH→GT, patients assigned to VEH in the double-blind trials who were newly exposed to GT in the open-label extension

Supplemental Table 2. Safety Outcomes Over Time in the Open-Label Extension According to Treatment Assignment in Double-Blind Lead-in Trials

	0 to 4 weeks N=550		>4 to 12 weeks N=537		>12 to 24 weeks N=479		>24 to 36 weeks N=417		>36 weeks to EOS N=365	
	GT→GT n=361	VEH→GT n=189	GT→GT n=350	VEH→GT n=187	GT→GT n=313	VEH→GT n=166	GT→GT n=270	VEH→GT n=147	GT→GT n=237	VEH→GT n=128
Drug withdrawal due to TEAE	16 (4.4)	5 (2.6)	12 (3.4)	2 (1.1)	11 (3.5)	1 (0.6)	3 (1.1)	0	1 (0.4)	0
TEAEs reported in ≥5% of patients										
Dry mouth	26 (7.2)	33 (17.5)	14 (4.0)	9 (4.8)	9 (2.9)	10 (6.0)	8 (3.0)	7 (4.8)	3 (1.3)	2 (1.6)
Vision blurred	8 (2.2)	3 (1.6)	7 (2.0)	7 (3.7)	3 (1.0)	4 (2.4)	2 (0.7)	3 (2.0)	3 (1.3)	1 (0.8)
Application site pain	11 (3.0)	5 (2.6)	7 (2.0)	2 (1.1)	4 (1.3)	1 (0.6)	6 (2.2)	0	3 (1.3)	0
Nasopharyngitis	9 (2.5)	5 (2.6)	8 (2.3)	1 (0.5)	3 (1.0)	1 (0.6)	5 (1.9)	0	2 (0.8)	1 (0.8)
Mydriasis	5 (1.4)	3 (1.6)	4 (1.1)	4 (2.1)	7 (2.2)	2 (1.2)	4 (1.5)	1 (0.7)	2 (0.8)	0

Safety outcomes from the first application of study drug in the open-label trial are reported. The safety population includes patients receiving ≥1 dose of GT and having ≥1 post-Baseline assessment in the open-label extension.

EOS, end of study; GT, Glycopyrronium tosylate; GT→GT = patients assigned to GT in the double-blind trials who continued on GT in the open-label extension; VEH, vehicle; VEH→GT = patients assigned to VEH in the double-blind trials who were newly exposed to GT in the open-label extension