HYPERHIDROSIS

SHORT- AND LONG-TERM EFFICACY AND SAFETY OF GLYCOPYRRONIUM CLOTH FOR THE TREATMENT OF PRIMARY AXILLARY HYPERHIDROSIS

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Introduction: Glycopyrronium tosylate (GT) is a topical anticholinergic recently approved in the US for primary axillary hyperhidrosis in patients ≥9 years (glycopyrronium cloth, 2.4%). Patients completing either double-blind, vehicle (VEH)-controlled, 4-week, Phase 3 trial (NCT02530281; NCT02530294) could enter an open-label extension (NCT02553798) study.

Objective: Evaluate short- and long-term safety and efficacy of GT

Materials and Methods: Patients ≥9 years with primary axillary hyperhidrosis, sweat production ≥50mg/5min/axilla, Axillary Sweating Daily Diary (ASDD) severity (Item 2) ≥4, and Hyperhidrosis Disease Severity Scale (HDSS) ≥3 were randomized 2:1 to GT or VEH, applied once daily. Completers could receive open-label GT for up to an additional 44 weeks. Safety evaluation included treatment-emergent adverse events (TEAEs). Efficacy assessments included ASDD Item 2 response (≥4-point improvement; double-blind only), absolute change in sweat production, HDSS response (≥2-grade improvement), and Dermatology Life Quality Index (DLQI)/children's DLQI (CDLQI).

Results: 463 (GT) and 234 (VEH) patients were randomized, 426 (92.0%) and 225 (96.2%) completed, and 564/651 (86.6%) entered the open-label extension. At Week 4 (double-blind), GT resulted in greater ASDD Item 2 responses (59.5% vs 27.6%; P<0.001; coprimary) and higher levels of sweat reduction (median change from Baseline [mg] -79.8 vs -61.8; P<0.001; coprimary) compared to VEH. HDSS response was 59.1% GT versus 25.7% VEH (P<0.001), and greater improvements for GT versus VEH occurred for DLQI (-8.4 vs -4.7; P<0.01) and CDLQI (-8.1 vs -1.9; P<0.01). Improvements with GT were maintained for up to an additional 44 weeks of open-label treatment. Most TEAEs were mild, transient, and infrequently led to discontinuation; no new safety signals occurred with

long-term treatment.

Conclusions: GT applied once daily for up to 48 weeks (4-week double-blind+44-week open-label) was generally well tolerated, reduced sweating severity, decreased sweat production, and improved quality of life, offering a new treatment option for a condition associated with substantial patient burden.