AESTHETIC AND COSMETIC DERMATOLOGY (LASERS SEPARATE CATEGORY)

EVALUATION OF QM1114, A NOVEL READY-TO-USE LIQUID BOTULINUM TOXIN, IN AESTHETIC TREATMENT OF GLABELLAR LINES

Gary D. Monheit [1] - Mark S. Nestor [2] - Joel Cohen [3] - Mitchel P. Goldman [4] - Michael H. Gold [5] - Elizabeth H. Tichy [6] - Leonard Swinyer [7]

Total Skin & Beauty Dermatology Center, -, Birmingham, United States [1] - Center For Clinical And Cosmetic Research, -, Aventura, United States [2] - Aboutskin Dermatology And Dermsurgery, Pc, -, Englewood, United States [3] - Cosmetic Laser Dermatology, -, San Diego, United States [4] - Gold Skin Care Center, -, Nashville, United States [5] - Clinical Trials Of Texas, Inc., -, San Antonio, United States [6] - Dermatology Research Center, Inc, -, Salt Lake City, United States [7]

INTRODUCTION: Reconstitution of botulinum toxin type A formulations is typically required before injection. QM1114 is a novel ready-to-use liquid botulinum toxin type A formulation.

OBJECTIVE: To evaluate efficacy and safety of 3 doses of QM1114 in aesthetic treatment of glabellar lines (GLs).
MATERIALS AND METHODS: Toxin treatment-naïve subjects aged ≥18 years with moderate-to-very severe GLs at maximum frown and at least mild GLs at rest were eligible for this multi-centre, double-blind 6-month Phase II study (NCT02236312). Single treatment with QM1114 (total dose: 30 [102 subjects], 45 [103 subjects] or 60 units [103 subjects]) or placebo (51 subjects) was randomly assigned. Assessments included wrinkle severity, subject satisfaction and treatment-emergent adverse events (TEAEs).

RESULTS: 359 subjects aged 23-79 years received QM1114 or placebo. Day 14 responder rates (≥2-grade improvement in wrinkle severity) were high at maximum frown across all QM1114 groups (investigators'/subjects' assessment: 87%/75% [30 units], 83%/73% [45 units], 91%/86% [60 units], 6%/8% [placebo]). Changes in wrinkle severity from Baseline at maximum frown were significantly higher for all QM1114 groups versus placebo throughout the 6 months. Duration of response (median time to return to Baseline score at maximum frown) was at least 175-181 days or longer. In all QM1114 groups, satisfaction with treatment was high at Month 1 (90-98% of subjects 'very satisfied' or 'satisfied') through Month 6 (72-80% of subjects 'very satisfied' or 'satisfied'). Treatment-related TEAEs affected ≥1% of subjects in any QM1114 group and exemplified as mild-to-moderate injection-site pain, headache, eyelid ptosis, injection-site pruritus, injection-site swelling, and eyelid oedema. No serious treatment-related TEAEs were observed.

CONCLUSIONS: At all doses, aesthetic GL treatment with QM1114 was highly effective with long duration, high subject satisfaction and an acceptable safety profile. In addition, the novel ready-to-use liquid formulation offered a convenient alternative to traditional botulinum toxin type A products requiring reconstitution before injection.