208 Once-Daily Fluticasone Furoate Nasal Spray 110 mcg Improves Quality of Life in Subjects with Perennial Allergic Rhinitis

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RATIONALE: Patients with perennial allergic rhinitis (PAR) experience symptoms that may affect their daily activities, sleep patterns, and emotional well-being, resulting in a significant impact on quality of life (QoL). The potential for improved QoL in subjects with PAR was assessed following treatment with fluticasone furoate nasal spray (FFNS), a novel enhanced-affinity intranasal steroid.

METHODS: The Rhinoconjunctivitis QoL Questionnaire (RQLQ), a 28-item, self-administered, disease-specific QoL instrument, was used to assess QoL changes in a 6-week global study (FFR106080) of 302 PAR subjects (≥12 years) randomized to once-daily FFNS 110 mcg or placebo. The RQLQ was administered at baseline and at end of study (Week 6/early withdrawal). A minimally important difference (MID) is a treatment difference of at least 0.5 in change from baseline in overall RQLQ score.

RESULTS: Baseline values for the overall RQLQ score and each of the seven domain scores were similar between treatment groups. For subjects treated with FFNS, the least square (LS) mean reduction from baseline was significantly greater than placebo for the overall RQLQ score (treatment difference: -0.646, $p < 0.001$). Similar results were observed for all seven individual domains: Activities, Sleep, Non-hay fever symptoms, Practical problems, Nasal symptoms, Eye symptoms, and Emotional problems (LS mean difference range:-0.450 to -0.884, $p < 0.001$) compared with placebo. A MID was also observed in favor of FFNS in the overall RQLQ and in all domains except the domain of Non-hay fever symptoms (-0.450).

CONCLUSIONS: FFNS 110 mcg once-daily provided statistically significant and clinically meaningful improvements in overall rhinitis-related QoL during a 6-week study of subjects with PAR.

Funding: GlaxoSmithKline

209 Duration of Action of Mometasone Furoate Nasal Spray in Subjects with Symptoms of Seasonal Allergic Rhinitis Induced in an Environmental Exposure Chamber

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RATIONALE: Environmental exposure chamber (EEC) is a controlled environment for inducing allergen responses similar to those occurring outdoors on peak pollen days. This study measured mometasone furoate nasal spray (MFNS) duration of action following initial dose and maintenance (7-day) dosing after ragweed exposure in EEC.

METHODS: Double-blind, placebo-controlled, parallel-group study randomized 310 subjects to 1 dose MFNS 200 mcg or placebo (Day 1); 155 subjects continued maintenance MFNS QD (n = 78) or placebo (n = 77) (Days 2-7). Subjects with seasonal allergic rhinitis who after priming visits had minimal threshold total nasal symptom score (TNSS ≥6/12: congestion, rhinorrhea, itching, sneezing; congestion score ≥2) were exposed to ragweed in EEC (Day 1). Subjects with minimal threshold score after 1.5 hours were randomized to receive initial dosing at 2 hours, and remained in EEC for 6 hours post-dosing. Duration of action was measured in 155 subjects who returned to EEC for second 4-hour ragweed exposure on Day 8 (22-26 hours post last dose). Instantaneous TNSS was assessed on Days 1 and 8.

RESULTS: On Day 8, MFNS group demonstrated statistically significantly greater improvements versus placebo: mean iTNSS 7.21 vs 8.41, respectively, after 2 hours in EEC ($P = 0.02$) (24 hours post last dose) and 7.50 vs 8.62, respectively, after 4 hours ($P = 0.03$). Numerically greater reductions in TNSS were observed in MFNS group compared with placebo on Day 1. Most treatment-emergent adverse events (MFNS = 15, 9.7%; placebo = 16, 10.3%) were mild/moderate.

CONCLUSIONS: MFNS 200 mcg QD in subjects with SAR produced statistically significant improvements in TNSS sustained over 24 hours.

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210 Fluticasone Furoate Nasal Spray Significantly Improves Nasal Symptoms and Peak Nasal Inspiratory Flow in Subjects with Perennial Allergic Rhinitis

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RATIONALE: Nasal symptoms and peak nasal inspiratory flow (PNIF) were evaluated in perennial allergic rhinitis (PAR) subjects treated with fluticasone furoate nasal spray (FFNS) or placebo.

METHODS: Subjects ≥ 12 years old with PAR (N = 302) received either FFNS 110 mcg or placebo once-daily for 6 weeks in this randomized, double-blind study (FFR106080). Primary endpoint: mean change from baseline (MCFB) over the entire treatment period in daily reflective Total Nasal Symptom Scores (rTNSS), comprised of 4 subject-rated individual symptom scores: nasal congestion, itching, rhinorrhea, and sneezing. The MCFB in daily reflective individual nasal symptoms and in daily PNIF measurements were included among the secondary endpoints. The primary analysis method was Analysis of Covariance. To assess the association between the subject-rated nasal symptom scores and PNIF, a more objective assessment, a post-hoc analysis of Pearson's correlation coefficient was performed.

RESULTS: The least squares (LS) MCFB in the daily rTNSS and all individual nasal symptoms showed statistically significant improvement with FFNS 110 mcg compared with placebo ($p < 0.001$). The LS MCFB in daily PNIF showed a similar response pattern, and increased significantly ($p = 0.004$) for FFNS (25.72 L/min) compared with placebo (17.35 L/min). Analysis indicated a moderate correlation between reduction in daily nasal congestion and increases in daily PNIF from Day 1 (-0.38) and throughout the treatment period (ranged from -0.35 to -0.46), regardless of treatment group.

CONCLUSIONS: Compared with placebo, FFNS significantly improved nasal symptoms with a corresponding significant increase in PNIF. A moderate correlation between improvement in nasal congestion and PNIF was seen in both groups.

Funding: GlaxoSmithKline

211 Once-Daily Fluticasone Furoate Nasal Spray Showed Greater Improvements in Relieving Nighttime Nasal Symptoms and Increasing Peak Nasal Inspiratory Flow Versus Oral Fexofenadine in Subjects With Seasonal Allergic Rhinitis (SAR)

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RATIONALE: Nighttime symptoms of SAR, particularly congestion, may reduce quality and quantity of sleep. Fluticasone furoate nasal spray (FFNS), a new enhanced-affinity intranasal corticosteroid, and oral fexofenadine (FEX), a non-sedating antihistamine, were compared using a validated nighttime symptom questionnaire (NSS), subject-rated nasal symptoms, and peak nasal inspiratory flow (PNIF), an objective measure of nasal obstruction.

METHODS: Subjects with SAR (n = 936) received either FFNS 110 mcg (312), fexofenadine 180 mg (311), or placebo (313) once daily for 2 weeks in this randomized, double-blind, double-dummy study (FFU109045). The primary endpoint was the mean change from baseline (MCFB) over the treatment period in the NSS, which assesses nasal congestion on awakening, nighttime awakenings, and difficulty going to sleep. Supportive