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Title: Lung function effects and safety of fluticasone furoate (FF)/vilanterol (VI) in patients with COPD: Mid-high dose assessment

Fernando 11672 Martinez fmartine@med.umich.edu MD ¹, Joseph 11673 Boscia bronchnu@aol.com MD ², Gregory 11674 Feldman gfeld3232@aol.com MD ³, Catherine 11675 Scott-Wilson catherine.a.scott-wilson@gsk.com ⁴, Sally 11676 Kilbride sally.5.kilbride@gsk.com ⁵, Leonardi 11677 Fabbri leonardo.fabbri@unimore.it MD ⁶, Peter M.A. 11678 Calverley pmacal@liverpool.ac.uk MD ⁷ and Courtney 11679 Crim courtney.c.crim@gsk.com MD ⁴. ¹ Department of Medicine, University of Michigan, Ann Arbor, United States ; ² Clinical Research, CU Pharmaceutical Research, Union, United States ; ³ Clinical Research, S. Carolina Pharmaceutical Research, Spartanburg, United States ; ⁴ Respiratory Medicine Development Center, GlaxoSmithKline, Research Triangle Park, United Kingdom ; ⁵ Department of Oncology Haematology and Respiratory Diseases, University of Modena & Reggio Emilia, Modena, Italy and ⁶ Clinical Science Centre, University Hospital Aintree, Liverpool, United Kingdom .

Body: Rationale: FF/VI is a novel once-daily (OD) inhaled corticosteroid/long-acting beta₂ agonist in development as combination therapy for COPD. Objective: To evaluate the efficacy and safety of FF/VI (200/25 and 100/25) vs placebo (PBO), FF (200 and 100mcg) and VI (25mcg), given OD via novel dry powder inhaler in moderate-severe COPD patients for 168 days. Methods: A multicentre, randomised, PBO-controlled, double-blind, parallel-group study (N=1224 (ITT)). Co-primary endpoints: weighted mean (wm) FEV₁ 0–4h (Day 168) to assess the contribution of VI, and trough FEV₁ (Day 169) to assess the contribution of FF and 24h duration of VI. Additional endpoints included CRQ-SAS dyspnoea, and safety. Results: Co-primary endpoints, see Figure. Treatment differences from PBO for dyspnoea scores were -0.12, -0.01, 0.07, 0.24 and 0.10 for FF 100, 200, VI 25, FF/VI 100/25, 200/25, respectively. On-treatment AEs were similar between active treatment groups (38–47%) and PBO (47%). No treatment effects on 24h urinary cortisol, laboratory values, or cardiac monitoring parameters were seen.

Conclusion: Addition of VI to FF produced a clinically significant improvement in wmFEV₁ (0-4h). Addition of FF to VI provided numerical improvements only in trough FEV₁. FF/VI at both strengths was superior to PBO for both primary endpoints. All treatments were well tolerated. Funded by GSK (H2C112207; NCT01054885).