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

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Body: Rationale: FF/VI is in development as a novel once-daily (OD) inhaled corticosteroid/long-acting beta$_2$ agonist combination therapy for COPD. Objective: To evaluate the efficacy and safety of FF/VI (100/25 and 50/25mcg) vs placebo (PBO), FF (100mcg), and VI (25mcg), given OD via a novel dry powder inhaler for 168 days in moderate-severe COPD patients. Methods: A multicentre, randomised, PBO-controlled, double-blind, parallel-group study (N=1030 (ITT)). Co-primary endpoints: weighted mean (wm) FEV$_1$ 0–4h (Day 168) to assess the contribution of VI, and trough FEV$_1$ (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. FF/VI 100/25 was numerically superior to components on dyspnoea score (treatment differences from PBO =0.30 vs 0.06 [FF] and 0.14[VI]). On-treatment AEs were more frequent with active treatment (54–60%) than PBO (48%). There were no treatment effects on 24h urinary cortisol, laboratory values, or cardiac monitoring parameters.

Conclusion: Addition of VI to FF produced a clinically significant improvement in wmFEV$_1$ (0-4h). Addition of FF to VI provided numerical improvements only in trough FEV$_1$. Combination therapy was superior to PBO for both co-primary endpoints. All treatments were well tolerated. Funded by GSK (HZC112206; NCT01053988).