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Title: Efficacy of combination fluticasone furoate/vilanterol (FF/VI) and salmeterol/fluticasone propionate (SFC) over 12 weeks in patients with COPD

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Body: Introduction: The novel combination of FF, an inhaled corticosteroid and VI, a long-acting beta$_2$ agonist, is under development as a once-daily (OD) therapy for COPD and asthma. Objectives: To compare the efficacy of OD FF/VI and twice-daily (BD) SFC in moderate-to-severe COPD. Methods: In a randomised, double-blind, double-dummy, parallel-group study, COPD patients (mean post-bronchodilator %predicted FEV_1 = 48%) received FF/VI 100/25mcg OD AM (N=266) via a novel dry powder inhaler or SFC 50/500mcg BD (N=262) via DISKUS™. Primary efficacy: change from baseline in 0–24h weighted mean (wm) FEV_1. Secondary endpoints included time to 100mL FEV_1 improvement over baseline on Day 1 (speed of onset), SGRQ-C; safety endpoints included adverse events (AEs). Results: There were non-significant trends favouring FF/VI (130mL) versus SFC (108mL) for wmFEV_1 (22ml [95%CI: –18,63], p=0.282) and speed of onset; FF/VI=16min, SFC=28min (p=0.280). A clinically meaningful improvement (–4.8) in SGRQ-C score was seen with FF/VI, but not SFC (–3.3), though the difference (–1.5 [95%CI: –3.9, 0.9]) was not statistically significant (p=0.215). Both treatments were well tolerated. 3 (1%) and 6 (2%) patients in the FF/VI and SFC arms experienced serious AEs; the same numbers withdrew as a result of on-treatment AEs. Safety profiles, including pulse rate, were similar. Conclusions: OD FF/VI and BD SFC improved lung function in patients with moderate-to-severe COPD without substantial safety concerns. Primary and secondary efficacy outcomes were numerically but not statistically superior for FF/VI vs SFC. Funded by GSK (HZC113107; NCT01342913).