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Title: Efficacy of the novel inhaled corticosteroid, fluticasone furoate (FF)/long-acting beta$_2$-agonist, vilanterol (VI) combination in reducing COPD exacerbations

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Body: Introduction: FF/VI is in development as once-daily (OD) combination therapy for COPD. Objectives: Assess effect of FF/VI on exacerbation rates in COPD compared to VI. Safety is described separately. Methods: In two replicate 1 year studies (HZC871;N=1622,HZC970;N=1633), after a 28 day run-in with ADVAIR DISKUS® 250/50mcg subjects received FF/VI 50/25, 100/25, 200/25mcg or VI 25mcg OD. Primary endpoint was the annual rate of moderate/severe exacerbations (MSE). Secondary efficacy endpoints included time to first 1st MSE and trough FEV_1. Results: Rate ratios (95%CI) for MSE with FF/VI vs VI (by-study & pooled data) are shown (Figure). There was a reduction in risk in time to 1st MSE vs VI ($p \leq 0.036$) for FF/VI 200/25 (HZC970 & pooled) and 100/25mcg (all). Trough FEV_1 vs VI at week 52 was greater ($p \leq 0.011$) for all FF/VI strengths in HZC871 (50/25=41mL, 100/25=58mL, 200/25=64mL) and pooled data (50/25=38mL, 100/25=42mL, 200/25=46mL) but for 50/25 only (34 mL, p=0.034) in HZC970.

Conclusions: Addition of FF to VI reduced the annual rate of MSE and time to onset of 1st MSE, with evidence of a consistent effect of the 100/25mcg strength in individual studies and the pooled analysis.

Lung function improved at all strengths of FF/VI vs VI in pooled analysis. The safety of the combination is reported separately. Funded by GSK: HZC102871:NCT01009463, HZC102970:NCT01017952.