European Respiratory Society
Annual Congress 2012

Abstract Number: 3140

Publication Number: P2113

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: COPD - management **Keyword 2:** COPD - exacerbations **Keyword 3:** No keyword

Title: Safety of fluticasone furoate (FF), an inhaled corticosteroid in combination with vilanterol (VI), a long-acting beta agonist in management of COPD exacerbations

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Body: Introduction: FF and VI are in development as combined once-daily (OD) therapy for COPD Objectives: Assess the safety of FF/VI (3 strengths) and VI in COPD Methods: In two replicate 1 year studies, 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: annual rate of moderate/severe exacerbations (described separately). Safety endpoints included all, serious and fatal Adverse Events (AEs), Local Steroid Effects (LSE, including candidiasis), bone disorders (BD, including fractures) and pneumonia Results: Pooled safety findings are shown in the table.

	VI	FF/VI		
ITT: n(%)	25 (N=818)	50/25 (N=820)	100/25 (N=806)	200/25 (N=811)

AE*	575 (70)	620 (76)	621 (77)	622 (77)
AE* (drug-related)	113 (14)	169 (21)	134 (17)	140 (17)
Serious AE*	126 (15)	136 (17)	123 (15)	124 (15)
Fatal AE†	13 (2)	16 (2)	10 (1)	14 (2)
LSE*	96 (12)	142 (17)	121 (15)	140 (17)
BD*	9 (1)	24 (3)	27 (3)	21 (3)
Pneumonia*	27 (3)	48 (6)	51 (6)	55 (7)
Pneumonia Hazard Ratio (HR) (95%CI) vs VI		1.7 (1.1, 2.8) p=0.025	1.8 (1.2, 3.0) p=0.010	2.0 (1.3, 3.2) p=0.003
* On-treatment † On-/Post-treatment				

HR for LSE and BD were significantly higher for FF/VI vs VI in all comparisons except LSE at 100/25 (p=0.065)

Conclusions: In COPD patients FF/VI exhibited similar rates of serious and fatal AEs to VI, although rates of AE, BD, LSE and pneumonia were greater with FF/VI than VI alone. The efficacy of the combination is reported separately Funded by GSK: HZC102871:NCT01009463, HZC102970:NCT01017952.