European Respiratory Society
Annual Congress 2012

Abstract Number: 3151

Publication Number: P1794

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: Treatments **Keyword 2:** Asthma - management **Keyword 3:** No keyword

Title: Efficacy and safety of fluticasone furoate (FF)/vilanterol (VI) once daily (OD) for 24 weeks in persistent asthma

Paul M. 11737 O'Byrne obyrnep@mcmaster.ca MD [1], Eugene R. 11738 Bleecker ebleeck@wfubmc.edu MD [2], Eric D. 11739 Bateman Eric.Bateman@uct.ac.za MD [3], William W. 11740 Busse wwb@medicine.wisc.edu MD [4], Ashley 11741 Woodcock ashley.woodcock@manchester.ac.uk MD [5], Richard 11742 Forth richard.6.forth@gsk.com [6], Tom 11743 Toler tom.n.toler@gsk.com [7], Loretta 11744 Jacques loretta.a.jacques@gsk.com [8] and Jan 11745 Lötvall jan.lotvall@gu.se MD [9]. [1] Michael G DeGroote School of Medicine, McMaster University, Hamilton, Canada ; [2] Center for Genomics and Personalized Medicine, Wake Forest University Health Sciences, Winston-Salem, United States ; [3] Department of Medicine, University of Cape Town, South Africa ; [4] Department of Medicine, University of Wisconsin, Madison, United States ; [5] School of Translational Medicine, University of Manchester, United Kingdom ; [6] Quantitative Sciences Division, GlaxoSmithKline, Research Triangle Park, United States ; [7] Respiratory Medicines Development Center, GlaxoSmithKline, Research Triangle Park, United States ; [8] Respiratory Medicines Development Centre, GlaxoSmithKline, Uxbridge, United Kingdom and [9] Krefting Research Centre, University of Gothenburg, Sweden .

Body: Introduction: FF and VI are, respectively, a novel inhaled corticosteroid and long-acting beta$_2$ agonist in development as a combined OD therapy for asthma and COPD. Objectives: To compare the efficacy and safety of FF/VI with FF and fluticasone propionate (FP) in patients (≥12 years old; on ICS) with moderate-to-severe persistent asthma. Methods: Patients (N=586; intent-to-treat) received FF/VI 200/25mcg OD PM, FF 200mcg OD PM or FP 500mcg twice daily (AM/PM) for 24 weeks. Co-primary endpoints were change from baseline in trough (pre-bronchodilator) FEV_1 and weighted mean 0–24h serial FEV_1. Secondary endpoints were change from baseline in %rescue-free and %symptom-free 24h periods and Asthma Quality of Life Questionnaire (AQLQ) score. Safety assessments included adverse events (AEs), 24h urinary cortisol (UC) excretion, vital signs and ECG. Results: FF/VI improved trough FEV_1 (diff. 193mL and 210mL; both $p<0.001$) and weighted mean serial FEV_1 (diff. 136mL [p=0.048] and 206mL [p=0.003]) vs FF and FP. Significantly more %rescue-free (11.7 [p<0.001]) and %symptom-free (8.4 [p=0.01]) 24h periods were reported with FF/VI vs FF. There was no statistical difference between FF/VI and FF in AQLQ score. Incidence of AEs was similar across groups. No clinically significant difference was seen across treatments with respect to 24-h UC excretion, vital signs or ECG. Conclusions: Treatment with FF/VI over 24 weeks was associated with statistically greater improvements in lung function and asthma stability vs FF and FP, and was well tolerated in this asthma population. Funded by GSK (HZA106829; NCT01134042).