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Title: Efficacy and safety of once-daily (OD) fluticasone furoate (FF) 50mcg over 24 weeks in adults and adolescents with persistent asthma

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Body: Introduction: The OD FF 50mcg dose showed effectiveness in asthma patients (pts) uncontrolled by short-acting β_2 agonists (SABAs) in a 12-week dose-ranging study. Objective: To assess efficacy/safety of FF 50mcg OD compared with placebo (PBO) in pts with asthma uncontrolled by non-corticosteroid therapies and/or SABA. Methods: Randomised, double-blind, double-dummy, parallel-group study (N=347;ITT) of FF 50mcg in the PM via dry powder inhaler, FP (active control) 100mcg BD via DISKUS or PBO for 24 weeks. Endpoints (all Δ baseline): primary–trough (pre-bronch.) FEV_1; secondary–%rescue-free 24-h periods (powered; %RF), PM and AM PEF, %symptom-free 24-h periods (%SF). Safety was assessed throughout. Results: FF (126mL), FP (191mL) and PBO (89mL) increased trough FEV_1 at 24 weeks vs baseline. %RF: FF 28.9, FP 31.7, PBO 21.1. PM PEF (L/min): FF 24.9, FP 12.0, PBO 7.6. AM PEF (L/min): FF 30.0, FP 21.4, PBO 10.8. %SF: FF 25.1, FP 24.3, PBO 16.8. See Table for treatment differences. AE profile was broadly similar across groups; AEs of special interest: FP and PBO both 10%; FF 3%.

Conclusions: This study showed a small statistically significant improvement in trough FEV_1 with FP, but not FF, vs PBO in pts with persistent asthma uncontrolled by non-ICS therapy. Secondary endpoints showed variable results. No safety concerns were identified for FF or FP. Funded by GSK (FFA115285;NCT01436110).