FLUTICASONE PROPIONATE (Fp) AND FLUTICASONE PROPIONATE/SALMETEROL (FS) DELIVERED VIA MULTIDOSE DRY POWDER INHALERS (MDPI) FOR PERSISTENT ASTHMA

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Background: The step-wise approach to asthma management recommends using the lowest level of controller medication to maintain control. This study assessed the efficacy and safety of Fp MDPI and FS MDPI, a new inhaler that is intuitive and easy for asthma patients to use correctly while delivering multiple doses of inhaled medications. Methods: This phase 3, multicenter, double-blind, parallel-group study (FSS-AS-301; NCT02139644) evaluated asthmatic patients (≥12 years) treated with inhaled corticosteroids (ICS) or ICS/long-acting beta-agonists (Fp dry powder inhaler 50–500 mcg/day or equivalent for ≥1 month). After a 14- to 21-day run-in during which patients received beclomethasone dipropionate hydrofluoroalkane metered dose inhaler 40 mcg, twice daily (BID), patients randomly received Fp MDPI 50 mcg, Fp MDPI 100 mcg, FS MDPI 50/12.5 mcg, FS MDPI 100/12.5 mcg, or placebo BID for 12 weeks. Primary efficacy endpoints were changes from baseline in forced expiratory volume in 1 second (FEV₁) and serial spirometry at week 12. Safety was assessed by adverse events. Results: The full analysis set (FAS) and serial spirometry subset included 640 and 312 patients, respectively. Changes from baseline in FEV₁ in the FAS and the serial spirometry subset at week 12 were significantly greater for all active treatment groups versus placebo (p<0.05). At week 12, FS MDPI significantly improved FEV₁ from baseline at each dose versus corresponding Fp MDPI doses; serial spirometry results in the FS MDPI groups were significantly greater at all time points (0–12 hours post-dose) versus corresponding Fp MDPI groups (p<0.05). Over the 12 weeks, improvements were maintained from day 1 through study end. Adverse events were similar across groups and consistent with drug classes. Conclusions: Fp MDPI and FS MDPI significantly increased pulmonary function versus placebo; FS MDPI was significantly superior to Fp MDPI with a similar safety profile. Funding: Supported by Teva Pharmaceuticals.