European Respiratory Society
Annual Congress 2013

Abstract Number: 2225

Publication Number: P703

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: Asthma - management **Keyword 2:** Bronchodilators **Keyword 3:** Anti-inflammatory

Title: Comparison of HFA salmeterol-fluticasone (SFC) combination when given through breath actuated inhaler (BAI) and pressurised meter dose inhaler (pMDI) in patients with moderate-to-severe asthma

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Body: Incorrect coordination of actuation and inhalation of drugs through a pMDI often leads to poor control of asthma.The aim of this study was to demonstrate non-inferiority in terms of efficacy and safety of SFC 50/125 mcg when given with BAI in comparison to pMDI in patients with moderate-to-severe asthma. In this double-blind, double-dummy, prospective, active-control, parallel group, 12 weeks study, 150 asthma patients were randomized after 2 weeks of wash-out period to receive SFC through BAI or pMDI at a dose of 2 inhalations twice daily. The primary endpoint was change in morning peak expiratory flow rate (mPEFR). Spirometry and subject diary assessments were performed at 2, 4, 8 and 12 weeks. Adverse events were monitored at each visit. mPEFR improved significantly in both the groups after 12 weeks of therapy (50.7±69.4L/min in BAI and 48.8±72L/min in pMDI; $p<0.0001$) and difference between them was not significant (+1.9L/min; 95% CI (-0.9L, 4.7L)). Change in evening PEFR both at week 2 (26.9±31.9L/min vs. 16.8±26.6L/min) & week 4 (32.87±43.8L/min vs. 21.9±37.5L/min) was greater in the BAI group and difference was statistically significant ($p<0.05$). FEV_1, FVC, day & night time symptoms scores and rescue medication doses were similar in both the groups (all p values >0.05). 75% of study participant preferred BAI over pMDI during usability assessment. There were no differences in frequencies of AEs. HFA SFC when given with BAI demonstrated non-inferiority in terms of efficacy and safety in comparison to pMDI in

patients with moderate-to-severe asthma and was the preferred device.