European Respiratory Society
Annual Congress 2012

Abstract Number: 2521
Publication Number: P1798

Abstract Group: 5.1. Airway Pharmacology and Treatment
Keyword 1: Asthma - management Keyword 2: Treatments Keyword 3: Spirometry

Title: Beclometasone/formoterol administered via extrafine dry powder inhaler in controlled asthmatic patients: Comparison with pMDI and beclometasone monotherapy

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Body: Background: The fixed combination of beclometasone dipropionate and formoterol fumarate (BDP/FF) 100/6 µg pMDI (Foster®) is approved for treatment of adult asthmatic patients. In order to provide physicians and patients with an alternative drug delivery system for BDP/FF, a new dry powder inhaler the NEXThaler® has been developed, able to ensure consistent dosing in patients who prefer the use of dry powder inhalers. Aim: To compare efficacy and safety profile of BDP/FF NEXThaler® with BDP/FF pMDI or BDP DPI alone in adult patients with controlled asthma. Methods: 8-week randomised,double-blind, triple-dummy, 3-arm parallel-group clinical study. After 4-week run-in with BDP/FF pMDI 100/6 bid, 755 patients were randomised to receive bid BDP/FF NEXThaler® 100/6, BDP/FF 100/6 pMDI or BDP DPI 100. The primary end-point was change from baseline to the entire treatment period in average pre-dose morning PEF (mPEF). Results: Non-inferiority of NEXThaler® vs pMDI was shown for mPEF (LSmeans difference:-1.84L/min; 95%CI[-6.73;3.05]) and lower limit of the 95%CI was above the pre-defined non-inferiority margin of -15L/min. Superiority of both combinations over BDP DPI was shown (p<0.001) providing evidence of assay sensitivity of the study. Both BDP/FF formulations were statistically superior to BDP alone in terms of ACQ score (p=0.009 and 0.008) and % of rescue use-free days (p=0.033 and 0.006) as well as pulmonary function tests over the entire treatment period. No relevant drug related AEs were observed. Conclusion: NEXThaler® is an effective and well-tolerated alternative delivery device for treatment of asthmatic patients with BDP/FF.