European Respiratory Society
Annual Congress 2012

Abstract Number: 1461

Publication Number: P2189

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: COPD - management **Keyword 2:** COPD - exacerbations **Keyword 3:** Treatments

Title: Tolerability and efficacy of budesonide/formoterol via Turbuhaler® vs standard treatment in Japanese patients with moderate to severe COPD: 52-week phase III study results

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Body: Background: This study evaluated the tolerability and efficacy of budesonide/formoterol (BUD/FORM) vs standard COPD treatment (SCT) in Japanese patients with moderate to severe COPD. Methods: In this randomised, open-label, parallel-group, phase III study (NCT01070784), patients ≥40 years of age with moderate to severe COPD for ≥2 years received either BUD/FORM 160/4.5 µg 2 inhalations twice daily via Turbuhaler® or SCT (as judged by the investigator) for 52 weeks. Reliever medication: salbutamol via pMDI. Primary outcome: nature, incidence and severity of adverse events (AEs). Secondary outcome variables included: COPD symptoms, lung function and exacerbations. Results: 260 patients were randomised. BUD/FORM was well tolerated; 404 AEs were reported by 123 patients (94.6%) receiving BUD/FORM vs. 367 AEs by 112 patients (86.2%) on SCT. The majority of AEs were of mild or moderate intensity and the AE profile was similar in the two groups. The most commonly reported AEs (BUD/FORM vs SCT) were nasopharyngitis (42.3% vs 39.2%), COPD (10.8% vs 19.2%) and bronchitis (11.5% vs 11.5%). The frequency of pneumonia-related AEs was similar in both groups (13.1% vs 12.3%) while dysphonia was more frequent with BUD/FORM (5.4% vs 0.8%). Serious AEs were more frequent with SCT (26.2%) vs. BUD/FORM (19.2%). No deaths were reported. Efficacy of BUD/FORM was maintained over 52 weeks. Conclusions: BUD/FORM 160/4.5 µg 2 inhalations twice daily was well tolerated and efficacy was maintained during 52-week treatment in Japanese patients with moderate to severe COPD. Funding: AstraZeneca.