European Respiratory Society
Annual Congress 2012

Abstract Number: 3163
Publication Number: P2117

Abstract Group: 5.1. Airway Pharmacology and Treatment
Keyword 1: COPD - management **Keyword 2:** Pneumonia **Keyword 3:** Treatments

Title: Risk of pneumonia related to budesonide use in COPD: An updated pooled analysis

Prof. Don 12033 Sin Don.Sin@hli.ubc.ca MD [1], Dr. Donald 12034 Tashkin DTashkin@mednet.ucla.edu MD [2], Dr. Finn 12035 Radner finn.radner@astrazeneca.com [3], Dr. Ulf 12036 Sjobring ulf.sjobring@astrazeneca.com MD [3], Dr. Anders 12037 Thoren anders.thoren@astrazeneca.com MD [3], Prof. Peter 12038 Calverley pmacal@liverpool.ac.uk MD [4] and Dr. Stephen 12044 Rennard srennard@unmc.edu MD [5]. [1] Department of Medicine, University of British Columbia, Vancouver, Canada ; [2] Division of Pulmonary and Critical Care Medicine, David Geffen School of Medicine, Los Angeles, United States ; [3] Clinical Sciences, AstraZeneca R&D, Molndal, Sweden ; [4] School of Clinical Sciences, University of Liverpool, United Kingdom and [5] Internal Medicine Section of Pulmonary and Critical Care, Nebraska Medical Center, Omaha, United States .

Body: Background: A meta-analysis of 7 clinical trials reported no increase in the risk of pneumonia as an adverse event (AE) in COPD patients taking the inhaled corticosteroid (ICS) budesonide; however, others have reported a numerical increase. Recently, an eighth trial (NCT00419744) fulfilling the meta-analysis inclusion criteria has been completed. This updated meta-analysis includes data from all 8 clinical trials of budesonide. Methods: Patient data were pooled from 8 clinical trials of inhaled budesonide (320–1280 μg/day), with or without formoterol, vs control (placebo or formoterol alone) in patients with stable COPD and ≥6 months of follow-up. The primary analysis compared treatment groups for the risk of pneumonia as an AE or serious AE (SAE) during the trial or within 15 days of the trial end. Cox proportional hazards regression was used to analyse the data on an intention-to-treat basis. Results: Data from 8260 patients were included; 4616 received budesonide and 3644 received control treatment, with 3395 and 2647 patient-years of exposure to treatment, respectively. No statistically significant difference was found between the budesonide and non-ICS treatment groups for the occurrence of pneumonia as an AE (3.9% [n=179 patients] vs 3.3% [n=120]; HR 1.13, 95% CI: 0.90–1.43) or a SAE (1.8% [n=82] vs 1.6% [n=59]; HR 1.02, 95% CI: 0.72–1.43). Similarly, there was no statistically significant difference between the budesonide and non-ICS treatment groups for time to pneumonia as an AE (log-rank test 0.30) or a SAE (0.926). Conclusion: The updated pooled analysis shows that budesonide (320–1280 μg/day) does not increase the risk of pneumonia over 12 months in patients with COPD. Funding: AstraZeneca.