Pneumonia risk in COPD patients initiating extrafine Fixed Dose Combination (FDC) with beclometasone dipropionate (ef-FDC-BDP) versus long-acting bronchodilators (LABD)

David Price[1], William Henley[1], Victoria Carter[1], Derek Skinner[1], Rebecca Vella[1], Alberto Papi[2], Leonardo M Fabbri[3], Huib AM Kerstjens[4], Nicolas Roche[5], Dave Singh[6], Claus F Vogelmeier[7], Elif Şen[8], José Eduardo Delfini Cançado[9], Elena Nudo[10], Sara Barile[10], George Georges[11]

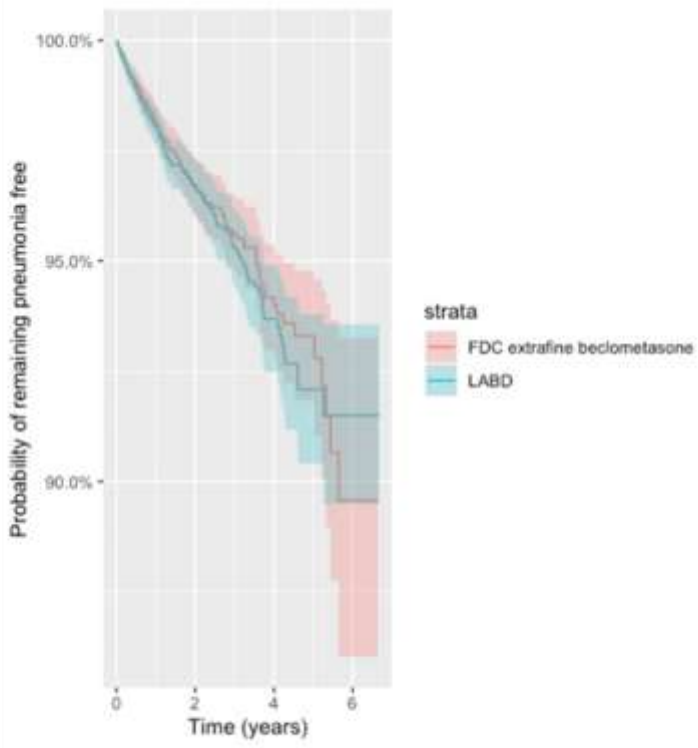
[1]Observational and Pragmatic Research Institute, Singapore; [2]Respiratory Medicine, University of Ferrara, Ferrara, Italy; [3]Section of Respiratory Medicine, Department of Morphology, Surgery and Experimental Medicine, University of Ferrara, Italy; [4]Department of Pulmonary Diseases, University of Groningen and University Medical Center Groningen, Groningen, The Netherlands; [5]Department of Respiratory Medicine, APHP-Centre University of Paris, Cochin Institute, Paris, France; [6]Division of Infection, Immunity & Respiratory Medicine, University of Manchester, Manchester University NHS Foundation Trust, United Kingdom; [7]Department of Internal Medicine, Pulmonary and Critical Care Medicine, University of Marburg, Member of the German Centre for Lung Research (DZL), Marburg, Germany; [8]Department of Pulmonary Medicine, Ankara University School of Medicine, Ankara, Turkey; [9]Santa Casa de São Paulo Medical School, São Paulo, Brazil;[10]Global Medical Affairs, Chiesi Farmaceutici, S.p.A., Parma, Italy; [11]Global Clinical Development, Chiesi Farmaceutici, S.p.A., Parma, Italy

Background: The use of extrafine inhaled corticosteroid (ICS) formulations in COPD treatment reduce exacerbations and allow lower doses possibly reducing pneumonia risk.

Aim: Compare pneumonia risk in COPD patients prescribed ef-FDC-BDP to those prescribed LABD alone.

Methods: Propensity matched historical cohort study was conducted using data from Optimum Patient Care Research Database. COPD patients aged ≥40 years with ≥1 year of continuous medical data who initiated ef-FDC-BDP or LABD were compared. Time to event analysis whilst on treatment was used to estimate pneumonia risk, as sensitive (physician-diagnosed) and specific (physician-diagnosed and x-ray or hospital admission confirmed) definition. Assessment of non-inferiority was conducted (upper boundary 15%).

Results: A total of 10,284 patients were matched. Initiation of ef-FDC-BDP was not associated with any difference in risk of pneumonia although non-inferiority criteria were not met: sensitive HR 0.95 (0.75-1.19); specific definition HR 0.97 (0.76-1.24) versus LABD.



Kaplan-Meier curve for the time to pneumonia (sensitive definition) for new users of ef-FDC-BDP and LABD

Conclusion: No significant differences were observed between ef-FDC-BDP and LABD pneumonia risk in propensity score matched analyses but non-inferiority was not reached.