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Title: COPD subtypes at greatest risk of pneumonia: Cluster analysis

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Body: Rationale: This analysis identifies COPD patient characteristics associated with greater risk of pneumonia with the aim to improve risk management and patient outcomes. Methods: Using two, pooled 1-year randomized trials (HZC102871, HZC102970) of 3,255 subjects with prior COPD exacerbations randomized to fluticasone furoate (FF)/vilanterol (VI) or VI, cluster analysis of baseline clinical and demographic data identified groups at greatest risk of a pneumonia or serious pneumonia event (e.g, hospitalization or death). A Cox proportional hazards model adjusting for study, smoking status, treatment, and region (random effect) was applied. Results: Five distinct COPD clusters were identified, with risk of first pneumonia and serious pneumonia generally increasing from left to right across clusters.

Patients at greater risk of first pneumonia had FEV_1/FVC < 46% and either BMI<19 (Cluster 5) or a pneumonia history and greater co-morbidities (Cluster 4) relative to Cluster 1. Independent of cluster, FF use was associated with pneumonia (Hazard Ratio (HR)=1.89, CI: 1.25-2.84) and serious pneumonia (HR=2.92, 95%CI 1.40-6.01). Conclusions: Cluster analysis identified COPD subject attributes associated with greater risk of pneumonia, including combinations of known risk factors. Cluster analysis can efficiently identify high-risk subgroups for serious safety outcomes and inform risk management strategies to optimize patient outcomes. (GSK-funded, WEUKBRE6624).