European Respiratory Society
Annual Congress 2013

Abstract Number: 2208

Publication Number: P696

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: COPD - management **Keyword 2:** Bronchodilators **Keyword 3:** Exacerbation

Title: A novel study design for the comparison between once-daily QVA149 and twice-daily salmeterol/fluticasone on the reduction of COPD exacerbations: The FLAME study

Prof. Jadwiga A. 4216 Wedzicha w.wedzicha@ucl.ac.uk MD [1], Prof. Marc 4217 Decramer Marc.Decramer@uzleuven.be MD [2], Prof. Jørgen 4218 Vestbo jorgen.vestbo@manchester.ac.uk MD [3], Dr. Nicola 4219 Gallagher nicola.gallagher@novartis.com [4], Dr. Han-Joo 4220 Kim han-joo.kim@novartis.com [5], Dr. Danny 4221 McBryan danny.mcbryan@novartis.com MD [6] and Dr. Donald 4223 Banerji donald.banerji@novartis.com MD [5]. [1] Department of Academic Respiratory Medicine, University College London, Royal Free Campus, London, United Kingdom ; [2] Respiratory Division, University Hospitals, University of Leuven, Leuven, Belgium ; [3] Respiratory Research Group, Manchester Academic Health Sciences Centre, Manchester, United Kingdom ; [4] Primary Care, Novartis Horsham Research Centre, Horsham, United Kingdom ; [5] Primary Care, Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States and [6] Primary Care, Novartis Pharma AG, Basel, Switzerland .

Body: Introduction Current COPD treatment guidelines recommend LABA/ICS for severe COPD patients (pts) with a history of exacerbations (exac). The 26wk ILLUMINATE study in moderate-to-severe COPD pts showed superiority of QVA149 vs. the LABA/ICS salmeterol/fluticasone (SFC) in lung function.[1] A novel study design to evaluate the effect of QVA149 vs. SFC on COPD exac in more severe pts with a history of exac is presented. Methods This multicenter, double-blind, active-controlled study will randomize ~3332 pts with moderate-to-very severe COPD (1:1) to once-daily QVA149 (110µg indacaterol/50µg glycopyrronium) or twice-daily SFC (50/500µg) for 52wks. The study will have a 1wk screening, a 4wk run-in where tiotropium rather than rescue therapy alone will be provided to all pts, a 52wk blinded treatment, and a 30 day follow-up period. Pts ≥40yrs, history of ≥1 COPD exac in the past 12 months requiring systemic glucocorticosteroids and/or antibiotics and post-bronchodilator forced expiratory volume in 1 second ≥25 and <60% predicted value will be included. Primary objective: to show that QVA149 is non-inferior to SFC for annual rate of all COPD exac (mild/moderate/severe). Secondary outcomes: evaluating potential superiority of QVA149 vs. SFC for annual rate of all exac, time to first COPD exac, lung function, health status, safety and tolerability. Conclusion The results from this study should elucidate the potential place in therapy for dual bronchodilation with QVA149 vs. LABA/ICS in a moderate-to-very severe COPD population with a history of exacerbations. Reference 1. Vogelmeier, C.F. et al. The Lancet Resp Med, online Dec 6, 2012.