

European Respiratory Society Annual Congress 2013

Abstract Number: 2217

Publication Number: P3635

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: COPD - management **Keyword 2:** Bronchodilators **Keyword 3:** Lung function testing

Title: Once-daily QVA149 demonstrates superior improvements in patient-reported dyspnea compared to tiotropium in patients with moderate-to-severe COPD: The BLAZE study

Prof. Donald A. 4106 Mahler Donald.A.Mahler@hitchcock.org MD ¹, Prof. Marc 4107 Decramer marc.decramer@uzleuven.be MD ², Prof. Anthony 4108 D'Urzo tonydurzo@sympatico.ca MD ³, Prof. Heinrich 4109 Worth med1@klinikum-fuerth.de MD ⁴, Dr. Tracy 4110 White tracy.white@novartis.com ⁵, Dr. Vijay 4111 Alagappan vijay.alagappan@novartis.com MD ⁵, Dr. Hungta 4214 Chen hungta.chen@novartis.com ⁵, Dr. Karoly 4117 Kulich karoly.kulich@novartis.com ⁶, Dr. Nicola 4118 Gallagher nicola.gallagher@novartis.com ⁷ and Dr. Donald 4126 Banerji donald.banerji@novartis.com MD ⁵.

¹ Department of Medicine, Geisel School of Medicine, Dartmouth, Hanover, United States ; ² Department of Respiratory Medicine, University Hospital, Katholieke Universiteit, Leuven, Belgium ; ³ Department of Family and Community Medicine, University of Toronto, Toronto, Canada ; ⁴ Departments of Pulmonology and Cardiology, Hospital Fürth, University Erlangen-Nürnberg, Fürth, Germany ; ⁵ Primary Care, Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States ; ⁶ Primary Care, Novartis Pharma AG, Basel, Switzerland and ⁷ Primary Care, Novartis Horsham Research Centre, Horsham, United Kingdom .

Body: Introduction Dyspnea, the most distressing symptom experienced by COPD patients, is not always adequately relieved by bronchodilator monotherapy. The BLAZE study evaluated the superiority of QVA149, a dual bronchodilator combining the long-acting β_2 -agonist indacaterol and the long-acting muscarinic antagonist glycopyrronium, versus placebo (PB) and tiotropium (TIO) for improvement in direct patient-reported dyspnea as assessed by the innovative self-administered computerized baseline and transition dyspnea index (SAC-BDI/TDI). Method In this multicenter, blinded, placebo-controlled, 3-period, crossover study, patients ≥ 40 yrs were randomized to once-daily QVA149 110/50 μ g, TIO 18 μ g, or PB. Improvements were assessed by the total TDI score after 6wks. Results 247 patients (mean age 62.8yrs; FEV₁ post-bronchodilator 56.1% predicted) were randomized; 77.3% completed the study. Patient-reported SAC-TDI total score was significantly improved with QVA149 compared to PB (p<0.001) and TIO (p=0.021). Least squares mean treatment differences between QVA-PB, QVA149-TIO and TIO-PB were 1.37, 0.49 and 0.88, respectively. The percentage of patients achieving ≥ 1 point improvement in SAC-TDI score was significantly higher with QVA149 (QVA149 34.7%, TIO 24.9%, PB 18.1%) compared to PB (odds ratio [OR] 2.65; p<0.001) and TIO (OR 1.66; p=0.037). The percentage of patients showing any adverse event with QVA149 (35.0%) was similar to TIO (35.5%) and slightly lower than PB (39.4%). Conclusion Dual bronchodilation with QVA149 provided statistically superior improvements in patient reported breathlessness compared to tiotropium and placebo.