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Title: Benefits of dual bronchodilation with QVA149 once daily versus placebo, indacaterol, NVA237 and tiotropium in patients with COPD: The SHINE study

Prof. Eric 500 Bateman eric.bateman@uct.ac.za MD [1], Gary T. 1596 Ferguson garytferguson@msn.com MD [2], Neil 1597 Barnes Neil.Barnes@bartshealth.nhs.uk MD [3], Nicola 1598 Gallagher nicola.gallagher@novartis.com [4], Yulia 1599 Green yulia.green@novartis.com [4], Rachael 1600 Horton rachael.horton@novartis.com [4], Michelle 1601 Henley michelle.henley@novartis.com [4] and Donald 1602 Banerji donald.banerji@novartis.com MD [5]. [1] Department of Medicine, University of Cape Town, South Africa ; [2] Pulmonary Department, Pulmonary Research Institute of Southeast Michigan, Livonia, MI, United States ; [3] London Chest Hospital, Barts Health NHS Trust, London, United Kingdom ; [4] Respiratory Department, Novartis Horsham Resarch Centre, Horsham, United Kingdom and [5] Respiratory Department, Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States .

Body: Background QVA149 is a novel once-daily dual bronchodilator combining the LABA indacaterol and the LAMA NVA237 (glycopyrronium) in development for COPD. Methods In a double-blind study, 2144 patients with moderate-to-severe COPD were randomized (2:2:2:2:1) to receive QVA149 110/50µg, indacaterol (IND) 150µg, NVA237 50µg (NVA), open-label tiotropium (TIO) 18µg or placebo (PBO), for 26 weeks. The primary endpoint was trough FEV_1 with QVA149 vs IND and NVA at 26 weeks. Results 89% patients completed the study. Trough FEV_1 at Week 26 was significantly greater with QVA149 vs PBO, IND, NVA and TIO (mean difference: 200, 70, 90 and 80mL, respectively; $p<0.001$). Significant improvement was also seen with QVA149 in other outcome measures evaluating lung function, dyspnea, health status and rescue medication use (table).

	Least squares mean treatment difference			
Day 1	QVA149–PBO	QVA149–IND	QVA149–NVA	QVA149–TIO
Trough FEV_1 (mL)+	190*	80*	80*	80*
FEV_1 $AUC_{0–4h}$ (mL)	220*	60*	30*	80*
Week 26				
Trough FEV_1 (mL)	200*	70*	90*	80*
FEV_1 $AUC_{0–4h}$ (mL)	340*	110*	140*	130*
FEV_1 $AUC_{0–24h}$ (mL)	320*	110*	110*	110*
Peak FEV_1 (L)(0–4h)	330*	120*	130*	130*

Transition Dyspnea Index focal score	1.09*	0.26	0.21	0.51†
St George's Respiratory Questionnaire total score	–3.01‡	–1.09	–1.18	–2.13†
Rescue medication use	–0.96*	–0.30†	–0.66*	–0.54*

+End of Day 1; *p<0.001; ‡p<0.01; †p<0.05

The incidence of adverse events was similar between groups (55% QVA149; 61% IND and NVA; 57% TIO; 58% PBO). Conclusion The LABA/LAMA combination of QVA149 once daily provided significantly superior, rapid and sustained bronchodilation vs PBO, IND, NVA and TIO, with significant symptomatic improvements and a safety profile similar to PBO.