

# European Respiratory Society Annual Congress 2013

Abstract Number: 2200

Publication Number: P3387

**Abstract Group:** 5.1. Airway Pharmacology and Treatment

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

**Title:** Dual bronchodilation with once-daily QVA149 improves lung function and reduces exacerbations in patients with COPD: The IGNITE trials

Dr. Donald 4700 Banerji donald.banerji@novartis.com MD <sup>1</sup>, Dr. Vijay 4701 Alagappan vijay.alagappan@novartis.com MD <sup>1</sup>, Dr. Yulia 4702 Green yulia.green@novartis.com <sup>2</sup>, Dr. Nicola 4703 Gallagher nicola.gallagher@novartis.com <sup>2</sup>, Dr. Angel 4704 FowlerTaylor angel.fowlertaylor@novartis.com <sup>1</sup>, Dr. Peter 4705 D'Andrea peter.dandrea@novartis.com MD <sup>1</sup> and Dr. Hungta 4706 Chen hungta.chen@novartis.com <sup>1</sup>. <sup>1</sup> Primary Care, Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States and <sup>2</sup> Primary Care, Novartis Horsham Research Centre, Horsham, United Kingdom .

**Body:** Introduction COPD treatment guidelines recommend the use of a second bronchodilator when patients are not controlled on single bronchodilator therapy. QVA149 is a dual bronchodilator which combines indacaterol (IND; a long-acting  $\beta_2$ -agonist) and glycopyrronium (GLY; a long-acting muscarinic antagonist) as a once-daily maintenance treatment for patients with COPD. Methods This summary of clinical efficacy includes data from 2667 patients from the QVA149 IGNITE clinical trial program. Endpoints presented here are lung function, COPD exacerbations, and safety. Results Improvements in all lung function parameters including trough, pre-dose and peak forced expiratory volume in 1 second (FEV<sub>1</sub>) with QVA149 were significantly greater (p<0.05) than placebo, IND, GLY, open-label tiotropium (TIO) and salmeterol/fluticasone (SFC) (Table). QVA149-treated patients had a significantly lower annualized rate of exacerbations compared to GLY and TIO (3.34 versus 3.92 and 3.89, respectively). Overall, QVA149 demonstrated a comparable safety profile to placebo, IND, GLY, TIO, and SFC.

Table: Treatment differences in spirometric assessments

FEV <sub>1</sub> (L)	Placebo	Indacaterol	Glycopyrronium	Tiotropium	Salmeterol/fluticasone
Trough	0.20*	0.07*	0.09*	0.08*	NP
Pre-dose	0.23*	0.06*	0.10*	0.09*	0.10*
Peak	0.33*	0.12*	0.13*	0.13*	0.15*

\*p<0.05; NP, not performed

**Conclusions** Data from the IGNITE studies demonstrates that once-daily QVA149 provides clinically relevant benefits for patients with COPD as demonstrated by improved lung function and reduced exacerbations and has a favorable safety profile.

