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Title: Once-daily QVA149 provides clinically meaningful improvements in lung function and clinical outcomes

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Body: Introduction QVA149 is a once-daily dual bronchodilator containing a fixed-dose combination of the long-acting β_2-agonist indacaterol (IND) and the long-acting muscarinic antagonist glycopyrronium (GLY) in development for the treatment of COPD. Here we present the pooled analysis from the SHINE, ILLUMINATE and SPARK studies of QVA149. Methods The SHINE study randomized 2144 patients (pts) to QVA149 110/50µg, IND 150µg, GLY 50µg, open-label tiotropium (TIO) 18µg or placebo (PB) for 26wks. The SPARK study randomized 2224 pts for 64wks to QVA149, GLY 50µg and TIO 18µg. In ILLUMINATE, 523 pts received QVA149 or twice-daily salmeterol/fluticasone (SFC) 50/500µg for 26wks. SHINE and ILLUMINATE evaluated lung function, Transition Dyspnea Index (TDI), St George's Respiratory Questionnaire (SGRQ) and rescue medication use. The SPARK study assessed annualized exacerbation rates, lung function, SGRQ and rescue medication use. Results QVA149 provided superior bronchodilation vs. all comparators with a rapid onset of action; improvements were sustained throughout the treatment periods. Significant treatment differences were observed for TDI focal score with QVA149 vs. PB (treatment difference=1.09; p<0.001), TIO (0.51; p=0.007) and SFC (0.76; p=0.003). SGRQ scores were significantly improved with QVA149 vs. PB, GLY and TIO. Pts in the QVA149 group used significantly less rescue medication vs. all comparators. Conclusion Once-daily QVA149 provides significantly superior, rapid and sustained bronchodilation vs. PB, IND, GLY, TIO and SFC, and significant symptomatic improvements in patients with moderate-to-severe COPD.