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Title: Once-daily QVA149 provides the same efficacy as the free combination of its monocomponents indacaterol and glycopyrronium: The BEACON study

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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) for the treatment of COPD. This study evaluated the safety and efficacy of once-daily QVA149 vs. the free combination of IND+GLY. Methods In this multicenter, double-blind, parallel group, non-inferiority study, patients with moderate-to-severe COPD were randomized (1:1) to QVA149 (110/50 μ g) plus placebo or IND (150 μ g) plus GLY (50 μ g) via the Breezhaler® device for 4wks. 184 randomized patients were planned to give the study 90% power to rule out that forced expiratory volume in 1 second (FEV₁) for QVA149 being 100mL worse than the concurrent administration of IND and GLY. Here we present the lung function results after 4wks. Results Of the 193 patients randomized (QVA149 [n=90], IND+GLY [n=103]); mean age: 64.9yrs; mean post-bronchodilator FEV₁: 54.0%, FEV₁/forced vital capacity (FVC): 46.0% predicted; 181 patients were analyzed and 96.9% completed. At Wk4, QVA149 showed similar improvement in trough FEV₁ as compared to IND+GLY (least squares mean [LSM] treatment [Tx] difference 5.0mL; 95% confidence interval [CI]: -51, 40). The LSM-Tx difference of FEV₁ area under curve (AUC_{0-4h}) for QVA149 vs. IND+GLY at Wk 4 was 12mL; 95% CI: -59, 34. Overall, safety profile was also similar for both groups. Conclusion Once-daily QVA149 offers the convenience of two bronchodilators in a single device while providing the same improvement in lung function compared to the co-administration of its monocomponents.