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Title: QVA149 administered once daily provides significant improvements in lung function over 1 year in patients with COPD: The ENLIGHTEN study

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Body: Background: QVA149 is a once-daily, fixed-dose combination of the long-acting β_2 -agonist indacaterol and the long-acting muscarinic antagonist NVA237 (glycopyrronium bromide) in development for the treatment of COPD. This study evaluated the long-term effect of QVA149 on lung function in patients with COPD. Methods: In a multicenter, double-blind, placebo-controlled study, patients with moderate-to-severe COPD were randomized (2:1) to receive QVA149 (110/50 μ g) or placebo (PBO) via a single-dose dry powder inhaler (Breezhaler®) for 52 weeks. Treatment was taken in the morning at the same time of day. Lung function was measured as forced expiratory volume in 1 second (FEV₁) and forced vital capacity (FVC) at 30 and 60 min post-dose at clinic visits over 52 weeks. Missing values were not imputed. Results: 338 pts (77% male, mean age 63 years; mean post-salbutamol FEV₁ 57% predicted, FEV₁/FVC 54%) were randomized to receive QVA149 (n=225) or PBO (n=113); 86% and 79% of patients respectively completed treatment. QVA149 significantly increased FEV₁ and FVC vs PBO at all assessment points (Table). QVA149 vs PBO differences in FEV₁ and FVC (mL) (all p<0.001):

FEV ₁	Day 1	Week 3	Week 6	Week 12	Week 26	Week 39	Week 52
30 min post-dose	156	246	268	235	271	231	248
60 min post-dose	201	267	276	256	275	277	257
FVC							
30 min post-dose	221	333	340	268	353	290	291

60 min post-dose	254	328	340	286	338	334	319
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Conclusion: QVA149 once daily provided rapid and clinically meaningful bronchodilation compared with PBO. No tachyphylaxis was observed and the bronchodilator effect was sustained over the 52-week treatment period.