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Title: Once-daily QVA149 significantly improves lung function and symptoms compared to twice-daily fluticasone/salmeterol in COPD patients: The ILLUMINATE study

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Body: Background QVA149 is a novel dual bronchodilator combination of the LABA indacaterol and the LAMA NVA237 (glycopyrronium), in development for the treatment of COPD. QVA149 once daily (QD) vs salmeterol/fluticasone (SFC) twice daily (BID) was evaluated in moderate-to-severe COPD patients with no history of exacerbations in the previous year. Methods In a double-blind, double-dummy, parallel-group study, 523 patients (QVA=258, SFC=264) were randomized to receive QVA149 110/50 µg QD (via the Breezhaler device®) or SFC 500/50 µg BID (via the Accuhaler device®) for 26 weeks. Results Mean age was 63 years; mean post-bronchodilator FEV_1 60% predicted. Mean FEV_1 $AUC_{0–12h}$ at Day 1 and Weeks 12 and 26 (primary endpoint) was significantly higher with QVA149 vs SFC ($p<0.001$ for all comparisons; table).

	Least squares mean treatment difference (mL)		
	Pre-dose trough FEV_1	Peak FEV_1	FEV_1 $AUC_{0–12h}$
Day 1	–	70*	70*
Week 12	90*	150*	120*
Week 26	100*	150*	140*

*$p<0.001$

Serial spirometry showed significantly higher and clinically meaningful improvements in FEV_1 with QVA149 vs SFC at all timepoints from 5 min to 12 h at Day 1 and Weeks 12 and 26 ($p<0.001$). QVA149 significantly improved the Transition Dyspnea Index score vs SFC (treatment mean: 2.16 vs 1.41, respectively;

p=0.003), reduced rescue medication use (–0.39 puffs/day; p=0.019) and improved other lung function measures (table) over 26 weeks. The safety profile of QVA149 was similar to that of SFC. Conclusion QVA149 QD provided significant, sustained and clinically meaningful improvements in lung function vs SFC BID over 26 weeks, with significant symptomatic benefits.