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Title: Once-daily QVA149 demonstrates superior outcomes in COPD patients previously treated with fixed-dose long-acting β_2 -agonist/inhaled corticosteroid (LABA/ICS): The ILLUMINATE study

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Body: Introduction The ILLUMINATE study evaluated the superiority of the once-daily QVA149 110/50 μ g, a dual bronchodilator combining the LABA indacaterol and the LAMA glycopyrronium, compared to twice-daily LABA/ICS, salmeterol/fluticasone 50/500 μ g (SFC), in terms of efficacy, safety and tolerability in patients (pts) with moderate-to-severe COPD. This analysis reports the efficacy and safety of QVA149 vs. SFC in the sub-group population using fixed-dose LABA/ICS prior to study enrollment. Methods 122 pts on LABA/ICS prior to study entry were randomized to QVA149 (n=54) and SFC (n=68). FEV₁ area under the curve for 0-12h (AUC_{0-12h}), pre-dose trough FEV₁, rescue medication use, exacerbations and safety were assessed after 26wks. Results QVA149 significantly improved FEV₁ AUC_{0-12h}, pre-dose trough FEV₁ and reduced rescue medication use in COPD pts regardless of previous LABA/ICS use at study entry (Table). Number of exacerbations (QVA149: 23; SFC: 41) and pts with incidence of adverse events (QVA149: 50%; SFC: 55.9%) was numerically lower with QVA149.

Parameter	Treatment difference, QVA149 vs. SFC			
	Pts with LABA/ICS prior to baseline (n=122)		Overall pt population (N=522)	
	Wk 12	Wk 26	Wk 12	Wk 26
FEV ₁ AUC _{0-12h} , mL	180(34)*	160(38)*	120(16)*	140(19)*
Pre-dose trough FEV ₁ , mL	140(35)*	150(40)*	90(17)*	100(19)*
Rescue medication use, puffs/day	-0.56(0.34)	-0.71(0.34) [#]	-0.28(0.16)	-0.39(0.17) [#]

*p<0.001; [#]p<0.05

Conclusion In the subpopulation previously treated with LABA/ICS, QVA149 demonstrated significant improvements in lung function and rescue therapy use compared to SFC. These results were consistent

with the overall study population.