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Title: QVA149 once-daily is safe and well tolerated and improves lung function and health status in Japanese patients with COPD: The ARISE study

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Body: Introduction Once-daily (OD) QVA149 is a dual bronchodilator combining the long-acting β_2 -agonist indacaterol and long-acting muscarinic antagonist glycopyrronium. The ARISE study evaluated the long-term safety and efficacy of QVA149 in Japanese patients (pts) with moderate-to-severe COPD. Methods This 52wk study randomized pts to OD QVA149 110/50 μ g (via the Breezhaler® device) or open-label tiotropium (TIO) 18 μ g OD (via the Handihaler® device). Here we present the efficacy evaluating forced expiratory volume in one second (FEV₁), health status via the St. George's Respiratory Questionnaire (SGRQ) score and rescue medication use. Safety and tolerability were also assessed. Results 160 pts were randomized, 88.8% completed. Lung function, rescue medication use and SGRQ changes are in table. Majority of AEs were mild to moderate in severity. Incidence rate of AEs was 84.0% for QVA149 and 71.8% for TIO. AEs with >10% incidence in any group were nasopharyngitis (33.6 and 30.8%) and COPD worsening (26.9 and 20.5%) for QVA149 and TIO, respectively.

Lung function, rescue medication use and SGRQ change from baseline

	QVA149 N=119	TIO N=39
Pre-dose FEV ₁ (mL)		
Wk12	209 (172.5)	139 (156.2)
Wk24	198 (173.5)	115 (140.0)
Wk52	189 (176.2)	52 (168.8)
Inspiratory capacity (mL)		

Wk12	130 (316.3)	79 (350.2)
Wk24	130 (276.1)	-14 (388.4)
Wk52	93 (339.6)	81 (481.8)
Rescue medication use (puffs/day)		
Wk52	-0.6 (1.11)	-0.2 (0.84)
SGRQ change		
Wk12	-4.5 (10.91)	-2.7 (7.84)
Wk24	-4.5 (11.70)	-0.3 (8.16)
Wk52	-2.9 (10.99)	-0.6 (9.92)

All values in mean (SD)

Conclusions QVA149 improved lung function, health status and was safe and well tolerated in Japanese patients with COPD.