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Title: Dual bronchodilation with QVA149 and the free combination of indacaterol and glycopyrronium are equally safe and well tolerated in patients with COPD: The BEACON study

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Body: Introduction Once-daily (OD) QVA149 offers the convenience of two bronchodilators in a single device. This study compared QVA149 to the co-administration of its monocomponents, the long-acting β_2 -agonist (LABA) indacaterol (IND) and long-acting muscarinic antagonist (LAMA) glycopyrronium (GLY). Methods In this multicenter, double-blind, parallel group study, patients with moderate-to-severe COPD were randomized (1:1) to OD QVA149 (110/50 μ g) or IND (150 μ g)+GLY (50 μ g) via the Breezhaler® device for 4wks. Here we present safety results after 4wks. Results 193 patients were randomized, mean age: 64.9yrs, 96.9% completed. Daily rescue medication use was reduced by -0.42 and -0.49 puffs/day for QVA149 and IND+GLY, respectively over 4wks. Incidence of adverse events (AEs) was similar in both groups over 4wks (Table). Similar frequency of serious AEs was seen for QVA149 (4.4%) and IND+GLY (5.8%); no deaths were reported in either group. No clinically meaningful change in laboratory results, vital signs or ECGs in any group was observed.

	QVA149, N=90	IND+GLY, N=103
Any AEs, n(%)	23 (25.6)	26 (25.2)
Primary system organ class		
Respiratory, thoracic and mediastinal disorders	10 (11.1)	7 (6.8)
Nervous system disorders	3 (3.3)	1 (1.0)
Vascular disorders	1 (1.1)	1 (1.0)
Renal and urinary disorders	0	3 (2.9)

Conclusion The safety and tolerability of once-daily QVA149 was similar to the free combination of its

monocomponents IND and GLY.