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Title: Cardio- and cerebro-vascular safety of QVA149: Results from a pooled analysis

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Body: Introduction QVA149 is a once-daily dual bronchodilator combining the long-acting β_2 -agonist indacaterol and long-acting muscarinic antagonist glycopyrronium in development for the treatment of COPD. Here we report the cardio- and cerebro-vascular (CCV) safety profile of QVA149. Methods This was a pooled analysis of 3153 patients with moderate-to-severe COPD from four QVA149 Phase III studies. Results CCV adverse events (AEs) and serious AEs occurring in ≥ 2 patients and major adverse cardiovascular events (MACE) in all treatment groups are summarized in the table.

Table: CCV AEs and SAEs occurring in ≥ 2 patients and MACE in all treatment groups

MedRA preferred term	QVA149 (N=1076)	Indacaterol (N=476)	Glycopyrronium (N=473)	Open-label tiotropium (N=519)	Salmeterol/fluticasone (N=264)	Placebo (N=345)
CCV AEs						
Any preferred term-total	19 (1.8)	12 (2.5)	14 (3.0)	9 (1.7)	6 (2.3)	9 (2.6)
Angina Pectoris	3 (0.3)	0	0	2 (0.4)	1 (0.4)	0
Atrial fibrillation	3 (0.3)	3 (0.6)	3 (0.6)	0	1 (0.4)	0
Ventricular extrasystoles	3 (0.3)	1 (0.2)	2 (0.4)	2 (0.4)	0	0
Supraventricular extrasystoles	2 (0.2)	0	1 (0.2)	1 (0.2)	0	1 (0.3)
	1 (0.1)	0	2 (0.4)	1 (0.2)	0	0

Cardiac failure congestive						
Myocardial ischemia	1 (0.1)	0	2 (0.4)	0	0	0
Sinus tachycardia	1 (0.1)	0	0	2 (0.4)	0	1 (0.3)
CCV serious adverse events (Any preferred term-total)	6 (0.6)	4 (0.8)	6 (1.3)	3 (0.6)	3 (1.1)	1 (0.3)
MACE - total	3 (0.3)	2 (0.4)	3 (0.6)	3 (0.6)	1 (0.4)	0

All values are n (%)

Conclusion The CCV safety profile of QVA149 and placebo were similar with no evidence of increased risk of CCV events with QVA149 versus all comparators in patients with moderate-to-severe COPD.