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Title: Safety of once-daily glycopyrronium in patients with severe-to-very severe COPD: The SPARK study

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Body: Introduction Glycopyrronium (NVA237) is a once-daily (OD) inhaled long-acting muscarinic antagonist for the treatment of COPD. Here we present the safety profile of glycopyrronium versus tiotropium in patients with COPD from the SPARK study. Methods This 64-week, multicenter, parallel-group, active-controlled study randomized patients ≥40 years with severe-to-very severe COPD and a history of exacerbations to receive double-blind QVA149 110/50µg or glycopyrronium 50µg (via the Breezhaler® device) or open-label tiotropium (via the Handihaler® device) 18µg OD. Safety was assessed by recording adverse events (AEs) and serious AEs (SAEs), and assessment of electrocardiograms, hematology, clinical chemistry, urinalysis, physical condition, and vital signs (pulse, blood pressure). Results The table shows the summary of safety results. The overall safety profile was similar for glycopyrronium and tiotropium.

Table: AEs, SAEs and deaths

	Glycopyrronium, N=740, n (%)	Tiotropium, N=737, n (%)
Total AEs	694 (94)	686 (93)
AEs leading to permanent discontinuation of study drug	86 (12)	67 (9)
Total SAEs	179 (24)	165 (22)
Deaths	22 (3)	25 (3)
Cardio- and cerebrovascular (CCV) SAEs	25 (3)	26 (4)
Atrial fibrillation/flutter events (New onset)	6 (1)	8 (1)

Major adverse cardiac events (MACE)-total	15 (2)	8 (1)
Non-fatal myocardial infarction (MI)	6 (1)	2 (0.3)
Unstable angina	0	0
Non-fatal stroke	4 (1)	2 (0.3)
Heart failure requiring hospitalization	3 (0.4)	3 (0.4)
Coronary revascularization (CABG or PCI)	4 (1)	2 (0.3)

Conclusion In the SPARK study, glycopyrronium showed an overall good safety profile in patients with severe-to-very severe COPD that was similar to tiotropium.