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Title: Once-daily NVA237 improves lung function in COPD patients: Pooled results of the GLOW1 and GLOW2 studies

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Body: Introduction NVA237 (glycopyrronium bromide) is safe and effective once-daily (QD) inhaled long-acting muscarinic antagonist for maintenance treatment of COPD. Methods This pooled analysis of the GLOW1 and 2 studies assessed the efficacy of NVA237 50µg QD vs placebo (PBO) and open-label tiotropium (TIO) 18µg QD over 26 to 52 wks in patients with moderate-to-severe COPD. Results include trough forced expiratory volume in 1 second (FEV₁) and forced vital capacity (FVC) at Day 1 and Wks 12, 26 and 52, 24-hr serial spirometry in a subset of patients, and FEV₁ AUC. Results 1888 subjects were randomized, 98.2% analyzed (NVA237=1059, TIO=267, PBO=528); male: 71.5%, mean age: 63.9yr, mean post-bronchodilator FEV₁: 55.5% predicted. All trough FEV₁ and FVC values for NVA237 and TIO were significantly greater than PBO (p<0.001) and NVA237 was numerically higher than TIO at all-time points (Table).

Table: Trough FEV₁ and FVC least square mean treatment difference (SE) from PBO (mL)

	FEV ₁		FVC	
	NVA237	TIO	NVA237	TIO
Day 1	98 (7.7)	88 (11.5)	187 (15.1)	178 (22.7)
Wk 12	103 (11.2)	88 (16.7)	190 (21.5)	172 (32.0)
Wk 26	125 (12.6)	78 (18.6)	205 (22.7)	133 (33.9)
Wk 52	108 (19.5)	89 (22.3)	179 (34.4)	180 (39.4)

The improvement in FEV₁ with NVA237 was seen immediately after the first dose on Day 1 (90mL at 5min

and 144mL at 15min versus PBO, $p < 0.001$) and sustained throughout the 52 Wk period. FEV₁ AUC for 0-4h, 0-12h, 0-24h and 12-24h for NVA237 was significantly greater than PBO ($p < 0.05$) and numerically greater than TIO on Day 1, Wk 12, 26 and 52. Conclusion NVA237 50µg QD provided rapid, sustained and clinically meaningful bronchodilation over 52 wks with efficacy similar to tiotropium.