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Title: Lung function efficacy of olodaterol QD delivered via Respimat® in COPD patients: Results from two 48-week studies

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Body: Background: The novel inhaled LABA olodaterol (O) has 24-h bronchodilator activity. Objective: To assess the efficacy of O QD in GOLD 2-4 COPD patients (pts). Methods: In two replicate, randomised, double-blind, placebo (P)-controlled, parallel-group studies, pts with post-bronchodilator FEV_1 <80% predicted normal and FEV_1/FVC <70% received O (5 or 10 µg) QD or P (both via Respimat®) for 48 weeks (wks) (Study 1: NCT00782210; Study 2: NCT00782509). Pts continued to receive usual care background COPD maintenance therapy, including SAMA, LAMA, ICS and xanthines. Co-primary end points were change from study baseline (response) in FEV_1 AUC_{0-3} and trough FEV_1 after 12 wks. Results: 624 (Study 1) and 642 (Study 2) pts were treated. In both studies, O 5 and 10 µg provided statistically significant improvements in the co-primary end points after 12 wks vs P.

	FEV_1 response: difference vs P, L			
	Study 1		Study 2	
	AUC_{0-3}	Trough	AUC_{0-3}	Trough
O 5 µg	0.172	0.091	0.151	0.047
O 10 µg	0.176	0.101	0.143	0.048

p<0.05 vs P

Results were consistent for FEV_1 AUC_{0-3} and trough FEV_1 response over 48 wks. Conclusions: O 5 and 10 µg QD over 48 wks provided significant improvements in lung function vs P in pts with moderate to very severe COPD with a magnitude of response in line with expectations for a bronchodilator used in a pt population on multiple concomitant COPD therapies. Funding: Boehringer Ingelheim.