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Title: The 24-h FEV_1 time profile of olodaterol QD delivered via Respimat® in COPD: Results from two 6-week studies

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Body: Background: Olodaterol (O) is a novel inhaled LABA. Objective: To evaluate the 24-h lung function profile of O QD in patients (pts) with GOLD 2-4 COPD. Methods: In two replicate, randomised, double-blind, placebo (P)-controlled, 6-week (wk), crossover studies, pts received O (5 or 10 µg) QD via Respimat®, tiotropium (T; 18 µg) QD via HandiHaler® or P for 6 wks (Study 1: NCT01040689; Study 2: NCT01040728). Pts continued with ICS and xanthines as background therapy. Co-primary end points were change from study baseline (response) in FEV_1 AUC_{0-12} and FEV_1 AUC_{12-24}; secondary end points were FEV_1 AUC_{0-3}, FEV_1 AUC_{0-24} and trough FEV_1 response after 6 wks of treatment. Results: 108 and 122 pts were treated in Studies 1 and 2, respectively. Significant bronchodilation vs P was evident over the full 24-h dosing interval for O and T QD.

Statistically significant ($p<0.001$) improvements were observed in all lung function end points with O 5 and 10 µg and T vs P.

	Mean FEV_1 responses after 6 wks: difference vs P, L					
	O 5 µg		O 10 µg		T 18 µg	
Study	1	2	1	2	1	2
AUC_{0-12}	0.185	0.197	0.207	0.221	0.173	0.221
AUC_{12-24}	0.131	0.153	0.178	0.170	0.123	0.164
AUC_{0-24}	0.158	0.175	0.192	0.191	0.148	0.192
AUC_{0-3}	0.206	0.214	0.215	0.245	0.182	0.235

Trough	0.133	0.134	0.147	0.143	0.097	0.158

$p<0.001$ vs P

Conclusions: These data confirm the 24-h lung function efficacy profile of O QD. Funding: Boehringer Ingelheim.