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Title: Symptomatic benefit of olodaterol QD delivered via Respimat® vs placebo and formoterol BID in patients with COPD: Combined analysis from two 48-week studies

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Body: Background: The novel LABA olodaterol (O) has 24-h bronchodilator activity. Objective: To evaluate the symptomatic benefit of O QD in patients (pts) with GOLD 2-4 COPD. Methods: In 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 via Respimat®, formoterol (F; 12 µg) BID via Aerolizer® or P for 48 weeks (wks; Study A: NCT00793624; Study B: NCT00796653). Pts continued to receive usual care background COPD maintenance therapy, including SAMA, LAMA, ICS and xanthines. In addition to FEV_1-based primary end points, TDI and SGRQ after 24 wks were identified as co-primary and key secondary symptomatic end points, respectively. Results: 904 (Study A) and 934 (Study B) pts were treated. In the primary analysis using a mixed model for repeated measures (MMRM; combined dataset), there was no significant difference in TDI focal score after 24 wks for O or F vs P. A post hoc analysis using pattern mixture modelling (PMM) to account for discontinued pts demonstrated statistical significance for O vs P. There were significant improvements in SGRQ total score with O, but not F, vs P after 24 wks using MMRM and PMM.

	Adjusted mean difference vs P after 24 wks (combined dataset)			
	TDI focal score		SGRQ total score	
	MMRM	PMM	MMRM	PMM
O 5 µg	0.3*	0.5†	-2.8†	-2.3†

O 10 µg	0.2*	0.5†	-3.4†	-3.1†
F 12 µg	0.2*	0.4*	-1.2*	-1.2*

*p=ns; †p<0.05

Conclusions: Lung function improvements with O QD translated into symptomatic benefit in COPD pts receiving usual care background therapy. Funding: Boehringer Ingelheim.