European Respiratory Society
Annual Congress 2013

Abstract Number: 2124

Publication Number: P764

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: Bronchodilators **Keyword 2:** Chronic disease **Keyword 3:** Pharmacology

Title: Lung function efficacy of olodaterol QD delivered via Respimat® vs placebo and formoterol BID in patients with COPD: Two 48-week studies

Andrea 16128 Koch andrea.koch@bergmannsheil.de MD [1], Emilio 16129 Pizzichini pizzichi@matrix.com.br [2], Alan 16130 Hamilton alan.hamilton@boehringer-ingelheim.com [3], Lorna 16131 Hart lorna.hart@boehringer-ingelheim.com [3], Lawrence 16132 Korducki lawrence.korducki@boehringer-ingelheim.com [4], Maria Cristina 16143 De Salvo dradesalvo@yahoo.com.ar [5] and Pierluigi 16151 Paggiaro lpaggiaro@dcap.med.unipi.it [6]. [1] Medizinische Klinik III for Pneumology, Allergology and Sleep-Medicine, University Hospital Bochum-Bergmannsheil, Bochum, Germany ; [2] NUPAIVA (Asthma Research Centre), Universidade Federal De Santa Catarina, Santa Catarina, Brazil ; [3] Boehringer Ingelheim, Burlington, ON, Canada ; [4] Boehringer Ingelheim Pharmaceuticals Inc., Ridgefield, CT, United States ; [5] Centro Médico Dra. De Salvo, Fundación Respirar, Buenos Aires, Argentina and [6] Dipartimento Cardio-Toracico e Vascolare, Università Di Pisa, Pisa, Italy .

Body: Background: Olodaterol (O) is a novel LABA with 24-h bronchodilator activity. Objective: To evaluate the efficacy 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 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; A: NCT00793624; B: NCT00796653). Pts continued to receive usual care background COPD maintenance therapy including SAMA, LAMA, ICS and xanthines. Co-primary lung function end points were change from study baseline (response) in FEV_1 AUC_{0-3} and trough FEV_1 after 24 wks. Results: 904 (A) and 934 (B) pts were treated. O 5 and 10 µg and F provided statistically significant improvements in co-primary end points after 24 wks vs P; there were no significant differences between O and F.

	FEV_1 response: difference vs P, L			
	A		B	
	AUC_{0-3}	Trough	AUC_{0-3}	Trough
O 5	0.151	0.078	0.129	0.053
O 10	0.165	0.085	0.154	0.069

F	0.177	0.054	0.150	0.042

$p<0.05$

Results were consistent for co-primary end points over 48 wks. Conclusions: O 5 and 10 µg QD significantly improved lung function vs P over 48 wks. Response magnitude was comparable to F BID and in line with expectations for a QD bronchodilator considering the pt population and concomitant therapy. Funding: Boehringer Ingelheim.