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Title: TIOSPIR®: Large scale trial of tiotropium Respimat® vs HandiHaler® (HH) in patients (pts) with COPD

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Body: Background: Direct comparisons of tiotropium Respimat® and HH in pts with COPD are limited. Prospective long-term data are needed to assess the relative effects on efficacy and safety. Aims and objectives: Compare safety and efficacy (exacerbations) of 5 µg and 2.5 µg once daily tiotropium Respimat® with 18 µg tiotropium HH in a phase IIIb study (TIOSPIR®). Methods: Randomized, active-controlled, double-blind, double-dummy, parallel-group, non-inferiority, event-driven, international multicentre (50 countries) trial of pts aged ≥40 y with COPD (postbronchodilator (postBD) FEV_1 ≤70% pred., FEV_1/FVC ≤70%), smoking history ≥10 pack-y. Primary endpoints: time to death (all-cause; non-inferiority analysis), time to first exacerbation (superiority analysis). Secondary endpoints: no. of: exacerbations, hospitalized exacerbations; time to: first hospitalized exacerbation, major cardiovascular AE. Time-to-event analyzed using Cox proportional hazards; no. of events: negative binomial model. Results: Enrollment completed in April 2011; 17135 pts began treatment (Table).

Baseline demographics	
Treated pts,N	17135
Age,y	65.0±9.1

Male,%	71.5
Current smoker,%	38.1
Smoking history, pack-y	43.8±24.8
FEV_1,L*	1.34±0.48
FEV_1, % pred*	48.3±13.9
FVC,L*	2.71±0.85
FEV_1/FVC*	0.499±0.114
GOLD stage,%	
I	0.3
II	48.5
III	40.1
IV	10.8
History of myocardial infarction,%	6.0
Coronary artery disease,%	15.2
Cardiac arrhythmia,%	10.6
Heart failure class,%	
None	92.1
I	3.1
II	4.1
III	0.6
IV	0.0
*PostBD. Data: mean±SD	

Conclusion: TIOSPIR® will provide robust data on relative safety and efficacy of tiotropium Respimat® vs HH from moderate to very severe COPD and across comorbidities. Funded by Boehringer Ingelheim.