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Title: Efficacy and safety of aclidinium bromide vs placebo and tiotropium in COPD: A phase IIIb study

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Body: Background: Maintaining significant bronchodilation throughout the entire day is important to improve COPD outcomes. Aim: To evaluate the 24-hour bronchodilatory efficacy and safety of aclidinium bromide vs tiotropium and placebo. Methods: In this randomized, double-blind study, 414 patients with COPD (FEV_1 1.6 L; 56% predicted) received aclidinium bromide 400 µg BID (metered dose; equivalent to aclidinium 322 µg delivered dose) via Genuair®[a], tiotropium 18 µg QD via HandiHaler® or placebo for 6 weeks. Endpoints included change from baseline in normalized FEV_1 AUC_{0-24} (primary) and FEV_1 AUC_{12-24} at Week 6, inhaler preference and safety. Results: Spirometry findings are summarized (Table). Genuair was preferred over HandiHaler (80% vs 11%; p<0.001). Patients were more willing to continue using Genuair than HandiHaler (89 vs 45; p<0.001 [0=not willing; 100=definitely willing]). AE incidence (28%, overall) was similar across groups. Few anticholinergic AEs (<2%) or SAEs (<3%) occurred in any group.

Change from baseline (difference from placebo), mL

	Aclidinium (N=171)	Tiotropium (N=158)	Δ
FEV_1 AUC_{0-24}			
Day 1	156*	117*	40†
Week 6	150*	140*	10
FEV_1 AUC_{12-24}			
Day 1	168*	100*	67†
Week 6	160*	123*	37
FEV_1 AUC_{0-12}			
Day 1	149*	136*	13

Week 6	138*	156*	-18
Trough FEV_1			
Day 1	141*	93*	48†
Week 6	141*	102*	38
Peak FEV_1			
Day 1	154*	139*	14
Week 6	180*	172*	8

LS mean differences: *p<0.001 vs placebo; †p<0.05 vs tiotropium (ANCOVA)

Conclusions: Aclidinium provided significant 24-hour bronchodilation vs placebo. Aclidinium and tiotropium had comparable efficacy after 6 weeks. [a]Registered trademark of Almirall S.A., Barcelona, Spain, for use within the EU, Iceland and Norway as Genuair®, and within the USA as Pressair™.