European Respiratory Society
Annual Congress 2012

Abstract Number: 3540

Publication Number: P2891

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: COPD - management **Keyword 2:** Bronchodilators **Keyword 3:** Quality of life

Title: Pooled analysis of twice-daily aclidinium bromide in COPD patients: Dyspnea and health status in the ACCORD-COPD I and ATTAIN trials

Paul 19705 Jones pjones@sgul.ac.uk MD [1], Edward 19718 Kerwin ekerwin@allergyasthmaso.com MD [2], Eric 19719 Bateman Eric.Bateman@uct.ac.za MD [3], Rosa 19720 Lamarca rosa.lamarca@almirall.com [4], Cynthia 19721 Caracta cynthia.caracta@frx.com MD [5] and Esther 19728 Garcia Gil esther.garciagil@almirall.com MD [6]. [1] Division of Clinical Sciences, St. George's University, London, United Kingdom ; [2] Clinical Research Institute, Medford, United States ; [3] Respiratory Medicine, University of Cape Town Lung Institute, Cape Town, South Africa ; [4] Clinical Statistics, Almirall, S.A., Barcelona, Spain ; [5] Clinical Development, Forest Research Institute, Jersey City, United States and [6] R&D Centre, Almirall, S.A., Barcelona, Spain .

Body: INTRODUCTION: Aclidinium is a novel, long-acting muscarinic antagonist in development for COPD treatment. Pooled analyses of dyspnea and health status data are shown here. METHODS: Patients (N=1389) were randomized (1:1:1) to aclidinium 200 μg, 400 μg or pbo BID for 12- and 24-weeks for the ACCORD and ATTAIN trials, respectively. Endpoints for both studies included TDI focal score, SGRQ total score and rescue medication use. RESULTS: The 200 μg and 400 μg groups showed statistically significant improvements from baseline to Week 12 in TDI focal score vs pbo (200 μg, 0.58, p<0.01; 400 μg, 0.92, p<0.0001), with numerically greater improvements seen with the higher dose. Clinically significant improvements (≥1-unit increase) in TDI at Week 12 were seen in a significantly higher proportion of patients in the 200 μg (51.3%, p=0.0001) and 400 μg (54.8%, p<0.0001) groups vs pbo (38.8%). Both doses resulted in statistically significant improvements from baseline to Week 12 in SGRQ total score vs pbo (200 μg, -5.10; 400 μg, -5.51, both p<0.0001). Clinically significant improvements (≥4-unit decrease) in SGRQ total score were seen in a significantly higher percentage of patients in the 200 μg (51.0%) and 400 μg (51.8%) groups (both p<0.001) vs pbo (38.1%) at Week 12. Both doses of aclidinium resulted in a significant reduction over pbo in daily rescue medication use (-0.6 puffs, 200 μg; -0.9 puffs, 400 μg; both p<0.005). CONCLUSIONS: Aclidinium 200 μg and 400 μg BID resulted in significantly more COPD patients who experienced clinically meaningful benefits in dyspnea and health status (>12% more in every case) as well as less rescue medication use versus placebo.