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

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.