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Title: Long-term safety of twice-daily aclidinium bromide in COPD patients: A one-year, double-blind study

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Body: INTRODUCTION: Aclidinium bromide is a novel, long-acting muscarinic antagonist currently under investigation for the maintenance treatment of COPD. Safety data from a long-term efficacy and safety trial of twice-daily (BID) aclidinium are presented here. METHODS: In this 52-week study, moderate-to-severe COPD patients were randomized (1:1) to receive aclidinium 200 µg or 400 µg BID. Safety was assessed via adverse events (AEs), vital signs, and 12-lead ECG. RESULTS: A total of 605 patients were randomized, and 602 (99.5%) were included in the safety population. Postbronchodilator FEV_1 and percent predicted at screening were (mean ±SD) 1.55 ±0.54 L and 52.3±13.2 L. The incidence of AEs was similar across the aclidinium 200 µg and 400 µg groups and most were mild or moderate. The most common AE and most frequently reported AE leading to discontinuation was COPD exacerbation, with a similar percentage of patients between groups who discontinued due to exacerbations [200 µg, 9 (2.9%); 400 µg, 8 (2.7%)]. The incidence of typically expected anticholinergic AEs was low and similar between groups (e.g. dry mouth: 200 µg, 1.3%; 400 µg, 2.7%; constipation: 200 µg, 2.9%; 400 µg, 1.7%). Cardiac and cerebrovascular AEs did not occur in a dose-related manner. The 200 µg and 400 µg groups had similar incidences of serious AEs, with values [n (%)] of 29 (9.3) and 29 (10.0), respectively. One patient in each treatment group died during the study (200 µg, biliary sepsis; 400 µg, subarachnoid hemorrhage), but neither death was deemed to be related to treatment. CONCLUSIONS: Twice-daily aclidinium 200 µg and 400 µg were safe and well tolerated over 52 weeks with a similar safety profile for both doses.