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Title: Aclidinium bromide reduces COPD exacerbations as defined by healthcare utilisation and EXACT: Results from ATTAIN

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Body: Introduction: COPD exacerbations can lead to considerable morbidity and mortality. Aims: ATTAIN investigated the effect of twice-daily (BID) aclidinium bromide, a long-acting muscarinic antagonist, on exacerbations in patients with moderate to severe COPD. Methods: In this 24-week, randomised, double-blind trial, 819 patients (mean±SD FEV_1 56.8±12.8% predicted) received aclidinium (200 µg or 400 µg) BID or placebo. Prior exacerbation history was not an inclusion criterion. Exacerbations were assessed by healthcare resource utilisation (HCRU; increased symptoms on ≥2 consecutive days requiring a change in treatment) and the EXAcerbations of Chronic pulmonary disease Tool (EXACT; persistent increase in total score of ≥9 points for ≥3 days or ≥12 points for ≥2 days). Results: EXACT captured more exacerbations per patient per year than HCRU (EXACT: 1.0, 0.98 and 1.39 for aclidinium 200 µg, 400 µg and placebo, respectively; HCRU: 0.43, 0.40 and 0.60, respectively). Exacerbation rates were significantly lower for both aclidinium doses compared with placebo and rate ratio differences were: EXACT: 200 µg, 0.72 [p=0.017] and 400 µg, 0.71 [p=0.012]; HCRU: 200 µg, 0.72 [p=0.043] and 400 µg, 0.67 [p=0.020]; corresponding to a rate reduction of about 28% with aclidinium using each method. Conclusions: More than twice as many events were recorded using EXACT compared with HCRU. Aclidinium 200 µg and 400 µg BID reduced exacerbations compared with placebo as assessed by HCRU and EXACT. The proportional improvement observed with treatment was similar irrespective of the method used. This study was supported by Almirall S.A., Barcelona, Spain, and Forest Laboratories, Inc., New York, USA.