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**Title:** Long-term efficacy of twice-daily acclidinium bromide in COPD patients: A one-year study

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**Body:** INTRODUCTION: Acclidinium bromide is a long-acting muscarinic antagonist currently under investigation for the long-term maintenance treatment of COPD. In this study, the long-term efficacy and safety of twice-daily (BID) acclidinium 200 µg and 400 µg in moderate-to-severe COPD patients were assessed. The efficacy results are reported here. METHODS: Patients were randomized (1:1) to receive acclidinium 200 µg or 400 µg BID in a double-blind manner. The primary endpoint was change from baseline to Week 52 in trough FEV<sub>1</sub>. Other efficacy parameters included change from baseline to Week 52 in peak FEV<sub>1</sub>, trough and peak FEV<sub>1</sub> by study visit, normalized FEV<sub>1</sub>AUC<sub>0-3</sub>, and change from baseline to Week 52 in SGRQ and EuroQol scores. RESULTS: A total of 605 patients were randomized to this study. Both acclidinium 200 µg and 400 µg BID resulted in improvements from baseline to Week 52 in trough and peak FEV<sub>1</sub> (Table), with numerically larger increases seen with the 400 µg dose. At study end, change from baseline in normalized AUC<sub>0-3</sub> FEV<sub>1</sub> was also improved for both groups, with greater improvements seen with the higher acclidinium dose (Table). Both treatment groups showed clinically significant improvements in SGRQ Total score and improvements in EuroQoL parameters from baseline to Week 52 (Table).

CONCLUSIONS: Treatment with acclidinium 200 µg or 400 µg BID results in benefits in lung function and health status in COPD patients over 1 year.