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Title: Efficacy and safety of umeclidinium/vilanterol compared with umeclidinium or tiotropium in COPD

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Body: Rationale: The long-acting muscarinic antagonist (LAMA) umeclidinium (UMEC) and long-acting beta$_2$ agonist vilanterol (VI) are in development as a combination treatment for COPD. Tiotropium (TIO) is a LAMA indicated for COPD. Objective: To evaluate efficacy and safety of two doses of UMEC/VI vs TIO or UMEC in patients with COPD. Methods: This was a 24-week, multicentre, double-blind, parallel-group, double-dummy study. Patients (N=869 [ITT]) were randomised 1:1:1:1 to once-daily UMEC/VI 125/25 mcg, UMEC/VI 62.5/25 mcg, UMEC 125 mcg or TIO 18 mcg via a dry powder inhaler. Primary endpoint was trough FEV_1 at Day 169. Secondary endpoint was weighted mean (WM) FEV_1 over 0–6 hours post-dose at Day 168. Safety evaluations included adverse events (AEs), vital signs, electrocardiography (ECG) and clinical laboratory measurements. Results: UMEC/VI 125/25 mcg showed statistically significant improvement in LS mean change from baseline in trough FEV_1 vs TIO (0.074 L, 95% CI: 0.025–0.123; p=0.003), but not vs UMEC 125 mcg (0.037 L, 95% CI: -0.012–0.087). An improvement was also shown by UMEC/VI 62.5/25 mcg vs TIO (0.060 L, 95% CI: 0.010–0.109) but not vs UMEC 125 mcg (0.022, 95% CI: -0.027–0.072). Both UMEC/VI doses showed larger improvements in LS mean change from baseline in 0–6-hour WM FEV_1 vs TIO and UMEC 125 mcg (0.070–0.101 L). The incidence of AEs was similar across treatments and no notable treatment-related changes were reported in vital signs, ECG or clinical measures. Conclusions: UMEC/VI (125/25 and 62.5/25 mcg) was well tolerated in patients with COPD and provided clinically-meaningful benefits in immediate and 24-hour lung function vs TIO. Funded by GlaxoSmithKline: DB2113374; NCT01316913.