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Title: Dose-finding study for tiotropium and olodaterol when administered in combination via the Respimat® inhaler in patients with COPD

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Body: Background: The novel long-acting β_2-agonist olodaterol (O) and long-acting muscarinic antagonist tiotropium (T) have a duration of action of at least 24 h in clinical studies. Dual administration may provide improved bronchodilation with convenient once-daily dosing. Objective: To determine the optimum once-daily combination of T+O delivered via the Respimat® inhaler in patients with COPD. Methods: In a randomised, double-blind, 4-period, incomplete crossover study, patients with post-bronchodilator forced expiratory volume in 1 second (FEV_1) of ≥30% and <80% of predicted normal received combinations of T and O, with both agents delivered via separate Respimat® inhalers, as well as O monotherapy, once daily for 4 weeks (NCT 01040403). The primary end point was trough FEV_1 response (L) at the end of week 4. Results: In total, 232 COPD patients (133 male; 99 female) received treatment. FEV_1 responses (trough and up to 6 h post-dose) for O 5 and 10 μg monotherapy were similar. For all doses of T, FEV_1 responses were significantly increased when added to O 5 and 10 μg. Dose ordering for T when added to O was evident. No safety or tolerability concerns were identified.

Conclusions: Addition of T to O resulted in significant improvements in FEV_1 versus O alone. These data support further investigation of T 2.5 and 5 μg combined with O 5 μg in the Phase III T+O clinical trial programme.