

Poster sessions

Conclusion Once-daily tiotropium Respimat® as add-on to ICS or ICS + LABA in patients with moderate to severe symptomatic asthma reduces airflow obstruction, apparently independent of their atopic and/or allergic status.

P230 ONCE-DAILY TIOTROPIUM RESPIMAT® IMPROVES LUNG FUNCTION IN PATIENTS WITH SEVERE SYMPTOMATIC ASTHMA INDEPENDENT OF LEUKOTRIENE MODIFIER USE

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Background Once-daily tiotropium Respimat®, a long-acting anticholinergic bronchodilator, has been shown in a Phase III programme to improve lung function and reduce severe exacerbation risk in patients with severe asthma who remain symptomatic despite using inhaled corticosteroids (ICS) + long-acting β_2 -agonist (LABA). Use of pre-trial leukotriene receptor antagonists (LTRAs) was not restricted; we analysed whether pre-screening LTRA use affected tiotropium Respimat® efficacy.

Methods In two Phase III, replicate, randomised, double-blind, placebo-controlled, parallel-group trials (PrimoTinA-asthma®: NCT00772538, NCT00776984), symptomatic patients received high-dose ICS + LABA and once-daily tiotropium 5 μ g or placebo (both delivered via the Respimat® SoftMist™ inhaler). LTRAs were permitted during run-in and treatment. Co-primary end points were peak and trough forced expiratory volume in 1 second (FEV₁) responses (difference from baseline) at 24 weeks. Subgroups were defined by pre-screening LTRA use: 'Yes'/'No'.

Results Of 912 randomised patients, 205 reported pre-screening LTRA use, 200 reported LTRA use during the treatment period and 187 had efficacy data at Week 24. Baseline characteristics were comparable between groups. Mean body mass index in LTRA 'Yes'/'No' groups was 27.8 kg/m² and 28.3 kg/m², respectively. Mean% predicted FEV₁ at baseline was 56% in both groups. Lung function responses improved independent of LTRA use: peak FEV₁ was 99 \pm 50 mL (p = 0.049) in the LTRA 'Yes'

group and 113 \pm 28 mL (p < 0.001) in the LTRA 'No' group (peak FEV₁ improvements independent of concomitant LTRA use [interaction p value=0.6742]). Trough FEV₁ (difference from placebo) was 90 \pm 46 mL (p = 0.052) in the LTRA 'Yes' group and 93 \pm 25 mL (p < 0.001) in the LTRA 'No' group (trough FEV₁ improvements independent of concomitant LTRA use [interaction p value = 0.5218]).

Conclusion Once-daily tiotropium Respimat® added to ICS + LABA improves lung function in patients with severe symptomatic asthma, independent of initial LTRA use.

P231 ONCE-DAILY TIOTROPIUM RESPIMAT®: SAFETY AND TOLERABILITY RESULTS FROM FIVE PHASE III TRIALS IN ADULTS WITH SYMPTOMATIC ASTHMA

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Background Tiotropium Respimat®, a once-daily long-acting anticholinergic agent, is effective as add-on to inhaled corticosteroids (ICS) \pm a long-acting β_2 -agonist (LABA) in adults with symptomatic asthma. Safety and tolerability are key issues in the development of new therapies or established therapies in new disease areas. We present key safety data from five Phase III, randomised, double-blind, parallel-group trials that evaluated the efficacy and safety of once-daily tiotropium Respimat® versus placebo in adults with symptomatic asthma. **Methods:** Two 48-week trials of tiotropium Respimat® 5 μ g (PrimoTinA-asthma®: NCT00776984, NCT00772538) in patients on high-dose ICS (\geq 800 μ g budesonide or equivalent) + LABA; two 24-week trials of tiotropium Respimat® 5 μ g and 2.5 μ g (MezzoTinA-asthma®: NCT01172808, NCT01172821) in patients on moderate-dose ICS (400–800 μ g budesonide or equivalent); one 12-week trial of tiotropium Respimat® 5 μ g and 2.5 μ g (GraziaTinA-asthma®: NCT01316380) in patients on low-dose ICS (200–400 μ g budesonide or equivalent). All tiotropium doses were delivered via the Respimat® SoftMist™ inhaler. **Results:**

Abstract P231 Table 1

	Tiotropium Respimat®						
	Tiotropium Respimat®	Placebo Respimat®	5 µg QD (n = 517)/ 2.5 µg QD (n = 519)	Salmeterol	Placebo ^a	Tiotropium Respimat®	Placebo Respimat®
%	5 µg QD (n = 456)	(n = 456)		(n = 541)	(n = 523)	5 µg QD (n = 155)/ 2.5 µg QD (n = 154)	QD (n = 155)
Any AE	73.5	80.3	57.3/58.2	54.3	59.1	32.3/31.2	29.0
Drug-related AE	5.7	4.6	7.4/6.9	5.2	5.4	1.3/1.3	1.3
Serious AE	8.1	8.8	2.1/2.3	2.0	2.7	0.6/0	0.6
Asthma	39.9	50.9	21.5/15.8	19.4	22.0	11.0/15.6	12.9
Bronchitis	5.5	4.4	2.1/1.7	1.7	1.0	1.9/0	0.6
Decreased peak expiratory flow rate	20.4	26.8	11.4/9.4	8.7	15.1	3.9/5.8	3.9
Headache	6.4	7.2	1.5/3.5	1.1	2.7	1.9/0.6	0
Nasopharyngitis	11.2	12.3	7.9/9.4	7.6	9.2	0.6/1.3	3.2
Upper respiratory tract infection	4.6	3.5	3.7/5.2	7.6	7.8	4.5/1.3	4.5

^aPlacebo Respimat® QD + placebo hydrofluoroalkane metered-dose inhaler BID BID, twice-daily; QD, once-daily