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MEETING ABSTRACT Open Access

Tiotropium respimat® add-on therapy reduces airflow obstruction in patients with symptomatic moderate asthma, independent of T_H2 inflammatory status

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Rationale

In patients with symptomatic asthma receiving ICS or ICS +LABA, Phase III studies have demonstrated improved lung function with tiotropium Respimat®, a once-daily long-acting anticholinergic bronchodilator. The efficacy of some treatments (eg ICS and omalizumab), appears higher in T_H2-high phenotypes, but no specific treatments are available that work equally well in both T_H2-high and T_H2-low phenotypes. We explored whether T_H2 biomarker status influenced responses to tiotropium in patients with moderate symptomatic asthma.

Methods

In two replicate Phase III, randomized, double-blind, placebo-controlled, parallel-group trials (NCT01172808/NCT01172821), patients with moderate symptomatic asthma, using medium-dose ICS (400-800 µg budesonide equivalent), were administered once-daily tiotropium Respimat® 5 µg or 2.5 µg, placebo, or salmeterol (active comparator without inferential analysis). Co-primary endpoints included peak and trough FEV_1 response (difference from baseline) at 24 weeks. Pre-planned analyses (pooled population) were performed in T_H2-high and T_H2-low subgroups defined at baseline as total serum IgE ≤ or >430 µg/L) or blood eosinophils ≤ or >0.6×10^9/L.

Results

Of 1545 patients in the full analysis set who received tiotropium or placebo, 915/1455 were reported with IgE >430 µg/L and 300/1461 with an eosinophil count of >0.6×10^9/L. Peak FEV_1 improved with tiotropium versus placebo, independent of IgE ($p<0.0001$ both doses) and eosinophil count ($p<0.0001$ both doses). Trough FEV_1 also improved with tiotropium versus placebo, irrespective of IgE ($p<0.0001$ both doses) and eosinophil count ($p<0.005$ both doses).

Conclusions

Once-daily tiotropium Respimat® as add-on to ICS reduces airflow obstruction in patients with moderate symptomatic asthma, independent of T_H2 phenotype, and thus may potentially provide an important therapeutic option.

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