**POSTER SESSIONS**

**P155**  
SAFETY OF TIOTROPIUM RESPIMAT® ADD-ON THERAPY IN PATIENTS AGED 6–17 YEARS WITH SYMPTOMATIC ASTHMA

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**Introduction and objectives**  
Two Phase II trials have shown tiotropium Respimat® (tioR) to be a well-tolerated bronchodilator in patients aged 12–17 and 6–11 years with symptomatic asthma. Here, we further assessed the safety and tolerability of once-daily (QD) tioR add-on therapy in Phase III trials in patients aged 6–17 years with symptomatic asthma.

**Methods**  
Data was analysed from three completed Phase III, randomised, double-blind, placebo-controlled, parallel-group trials: VivaTinA (NCT01634152), 12-week trial, patients aged 6–11 years; PensieTinA (NCT01277523), 12-week trial, patients aged 12–17 years; RubaTinA (NCT01257230), 48-week trial, patients aged 12–17 years. Patients received QD tioR 5 μg (2 puffs, 2.5 μg), QD tioR 2.5 μg (2 puffs, 1.25 μg) or QD placebo Respimat® (pboR; 2 puffs) as add-on to background therapy. Adverse events (AEs) were recorded and analysed descriptively by age: 6–11 years; 12–17 years.

**Results**  
1189 patients were treated: 6–11 years, n = 400; 12–17 years, n = 789. The frequency of patients with AEs was similar across all treatment arms, with a low incidence of drug-related and serious AEs; asthma and decreased peak expiratory flow rate were the most common AEs (Table). No deaths occurred.

**Conclusion**  
The AE profile and AE incidences were similar between tioR 5 μg, tioR 2.5 μg and pboR, as add-on to inhaled corticosteroid ± other controllers, in patients aged 6–17 years with symptomatic asthma.

**REFERENCES**


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**P156**  
EFFICACY, SAFETY AND TOLERABILITY OF ONCE-DAILY TIOTROPIUM RESPIMAT® ADD-ON THERAPY IN CHILDREN WITH MODERATE SYMPTOMATIC ASTHMA

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**Introduction and objectives**  
A Phase II trial has shown that tiotropium Respimat® (tioR) is an effective, safe, and well-tolerated bronchodilator in patients aged 6–11 years with moderate symptomatic asthma.1 To further assess the efficacy and safety of once-
The primary end point was peak FEV1 within 3 hours post-dosing (FEV1(0–3 h)). Secondary end points included trough FEV1 (key end point), FEV1 area under the curve (AUC) (0–3 h), and peak FVC (0–3 h); all measured as response (change from baseline) at Week 24. Adverse events (AEs) were analysed descriptively.

Results Of 403 patients randomised, 401 were treated. Baseline demographics and disease characteristics were balanced between treatment groups. TioR 5 µg and 2.5 µg provided statistically significant improvements in lung function versus pboR at Week 24 (Table) with adjusted mean change ± standard error peak FEV1 (0–3 h) improvements of 164 ± 31 ml (p < 0.0001) and 170 ± 31 ml (p < 0.0001), respectively. The frequency of patients with AEs was similar across treatment arms, with a low incidence of drug-related and serious AEs (Table); no deaths occurred. The most common AEs were asthma worsening/exacerbation (lower incidence in tioR 5µg and 2.5 µg [34.1% and 36.3%] vs pboR [43.5%]), decreased peak expiratory flow rate (21.5% and 23% vs 20.6%), nasopharyngitis (8.9% and 11.1% vs 9.9%) and respiratory tract infection (9.6% and 8.1% vs 12.2%).

Conclusion In patients aged 6–11 years with moderate symptomatic asthma, once-daily tioR add-on to ICS with or without other maintenance therapy significantly improves lung function compared with pboR. The safety profile of tioR was similar to that of pboR.

REFERENCE

Please refer to page A272 for declarations of interest in relation to abstract P156.