

µg (55.6%). Two patients each in the tioR 5 µg (6.5%) and pboR (5.9%) groups were reported with drug-related AEs. Three patients, all in the pboR group, were reported with serious AEs. Asthma exacerbation/worsening was reported by fewer patients in the tioR 5 µg and tioR 2.5 µg groups compared with the pboR group (Table).

**Conclusion** Once-daily tiotropium Respimat® add-on to maintenance therapy is well tolerated and may reduce exacerbations in pre-school children with symptomatic persistent asthma.

Please refer to page A272 for declarations of interest in relation to abstract P154.

### 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<sup>1</sup> and 6–11<sup>2</sup> 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

- 1 Vogelberg C, et al. *Respir Med* 2014;**108**:1268–76.
- 2 Vogelberg C, et al. *Respir Res* 2015;**16**:20.

### Abstract P155 Table 1 Summary of adverse events in the VivaTinA-asthma, PensieTinA-asthma and RubaTinA-asthma trials

n (%)	Tiotropium Respimat® 5 µg QD	Tiotropium Respimat® 2.5 µg QD	Placebo Respimat® QD
<b>VivaTinA-asthma®, 6–11 years</b>			
<b>Overall AEs</b>	<b>n = 130</b>	<b>n = 136</b>	<b>n = 134</b>
Patients with any AE	56 (43.1)	59 (43.4)	66 (49.3)
Patients with investigator-defined drug-related AEs	1 (0.8)	0	2 (1.5)
Patients with AEs leading to discontinuation	2 (1.5)	0	2 (1.5)
Patients with serious AEs	4 (3.1)	2 (1.5)	2 (1.5)
<b>AEs in &gt;5% pts in any treatment group, by preferred term</b>			
Asthma <sup>a</sup>	24 (18.5)	20 (14.7)	30 (22.4)
Decreased peak expiratory flow rate	15 (11.5)	15 (11.0)	20 (14.9)
Nasopharyngitis	6 (4.6)	6 (4.4)	11 (8.2)
<b>PensieTinA-asthma® and RubaTinA-asthma®</b>			
<b>Overall AEs</b>	<b>n = 264</b>	<b>n = 252</b>	<b>n = 273</b>
Patients with any AE	127 (48.1)	121 (48.0)	130 (47.6)
Patients with investigator-defined drug-related AEs	4 (1.5)	1 (0.4)	2 (0.7)
Patients with AEs leading to discontinuation	0	0	3 (1.1)
Patients with serious AEs	5 (1.9)	3 (1.2)	2 (0.7)
<b>AEs in &gt;5% pts in any treatment group, by preferred term</b>			
Asthma <sup>a</sup>	38 (14.4)	41 (16.3)	46 (16.8)
Decreased peak expiratory flow rate	11 (4.2)	18 (7.1)	21 (7.7)
Nasopharyngitis	25 (9.5)	19 (7.5)	21 (7.7)
Viral respiratory tract infection	11 (4.2)	11 (4.4)	14 (5.1)

Treated set. Percentages calculated using total number of patients per treatment as denominator. AE preferred terms defined by Medical Dictionary for Regulatory Activities version 16.1 or 18.0. Tiotropium Respimat® or placebo Respimat® administered as add-on to background therapy

<sup>a</sup>Represents asthma worsening or exacerbation

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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.<sup>1</sup> To further assess the efficacy and safety of once-