

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 8-K

**Current Report Pursuant
to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): **September 22, 2010**

THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation)

000-30319

(Commission File Number)

94-3265960

(I.R.S. Employer Identification Number)

**901 Gateway Boulevard
South San Francisco, California 94080
(650) 808-6000**

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

Today at the European Respiratory Society Annual Congress in Barcelona, Spain, GlaxoSmithKline plc presented two oral presentations: Phase 2 study of RELOVAIR™, a once-daily combination medicine of fluticasone furoate (FF), the inhaled corticosteroid (ICS), and vilanterol trifenate (VI), the long-acting beta₂ agonist (LABA) in patients with chronic obstructive pulmonary disease (COPD) and Phase 2b study of VI in patients with asthma. RELOVAIR™ is being developed for the treatment of patients with COPD or asthma under the LABA collaboration between GSK and Theravance, Inc. The two presentations are filed as Exhibit 99.1 and Exhibit 99.2 to this report and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Safety and efficacy of fluticasone furoate/vilanterol trifenate (FF/VI) in COPD patients
Exhibit 99.2	24h duration of the novel long-acting b ₂ agonist vilanterol trifenate in uncontrolled asthma

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THERAVANCE, INC.

Date: September 22, 2010

By: /s/ Michael W. Aguiar

Michael W. Aguiar
Chief Financial Officer

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EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Safety and efficacy of fluticasone furoate/vilanterol trifenate (FF/VI) in COPD patients
Exhibit 99.2	24h duration of the novel long-acting b2 agonist vilanterol trifenate in uncontrolled asthma

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Safety and efficacy of fluticasone furoate/vilanterol trifenate (FF/VI) in COPD patients

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C Crim⁵, L Sanford⁶, C Scott-Wilson⁵, B Haumann⁶

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⁴Lung Department, St. Olavs University Hospital of Trondheim, Trondheim, Norway

⁵Respiratory Medicine Development Centre, GlaxoSmithKline, RTP, USA

⁶Respiratory Medicine Development Centre, GlaxoSmithKline, London, UK

CONFLICT OF INTEREST DISCLOSURE

Jan Lötvall has the following, real or perceived conflicts of interest:

-Served as a consultant to, and received lecture fees from, or been sponsored to attend congresses by:

- AstraZeneca**
- GlaxoSmithKline**
- Merck Sharpe and Dohme**
- Novartis**
- Oriel Therapeutics**
- UCB Pharma**

ACKNOWLEDGEMENTS

- **Funded by GlaxoSmithKline**
- **Editorial support by Gardiner-Caldwell Communications, funded by GlaxoSmithKline**
- **Investigators and staff at the four study centres**

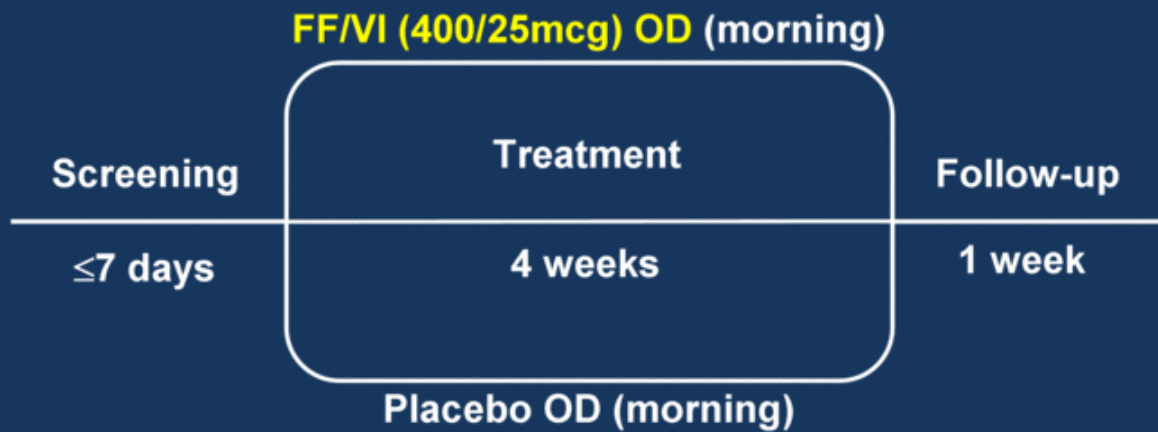
Background FF and VI combination

- Fluticasone furoate (FF)
 - Novel ICS - 24h activity
- Vilanterol trifenate (VI)
 - Novel LABA - 24h activity
 - 25mcg optimal dose
- FF and VI (**FF/VI**)
 - Developed as once-daily combination treatment for COPD and asthma
- Current ICS/LABA therapies are indicated twice-daily
- ICS/LABA therapies can be further improved

Objectives and endpoints, FF/VI once daily

- COPD
 - Safety
 - Tolerability
 - Efficacy
- Co-primary endpoints
 - Change in heart rate (Δ HR 0–4h)
 - Adverse events
- Secondary endpoints
 - Change in trough FEV₁ on Days 2, 15 and 29
 - Serial FEV₁ on Days 1 and 28
 - Time to \geq 100mL increase in FEV₁ on Day 1

Study design



- 40-80 years of age at Visit 1
- Clinical history of COPD (ATS/ERS)
- Current or prior smoking history of ≥ 10 pack years
- Post-salbutamol FEV_1/FVC ratio of ≤ 0.70
- Post-salbutamol FEV_1 between ≥ 40 and $\leq 80\%$ predicted at Visit 1

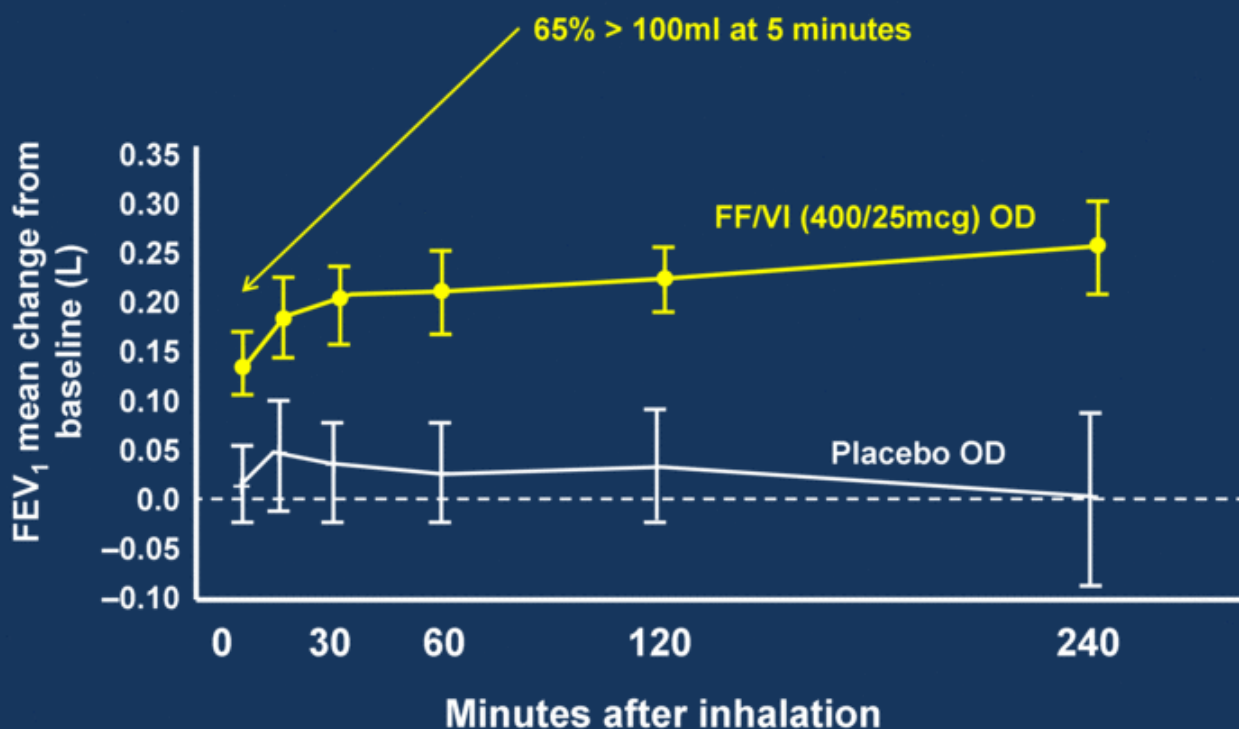
Intention To Treat (ITT):

- 60 randomised patients
 - 40 patients – **FF/VI (400/25mcg) OD**
 - 20 patients – placebo
- 5 patients withdrew
 - 3 adverse events (2 placebo)
 - 1 protocol deviation (placebo)
 - 1 lost to follow-up (placebo)

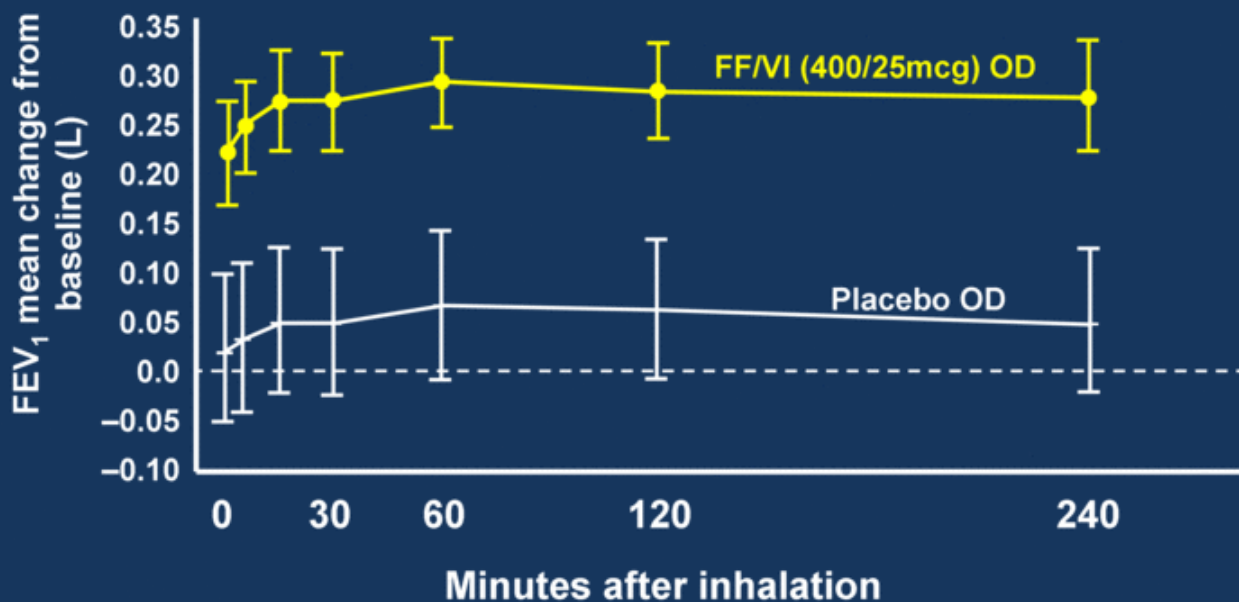
Demographics and lung function

- Similar between groups:
 - Mean age 63.6 years
 - 33% female
- Smoking history
 - 37% current smokers; 63% former smokers
 - Mean pack years = 33.8
- Screening lung function
 - Mean FEV₁ %: 59%
 - Mean FEV₁/FVC: 54%
 - Mean reversibility FEV₁: 15.6% (231mL)

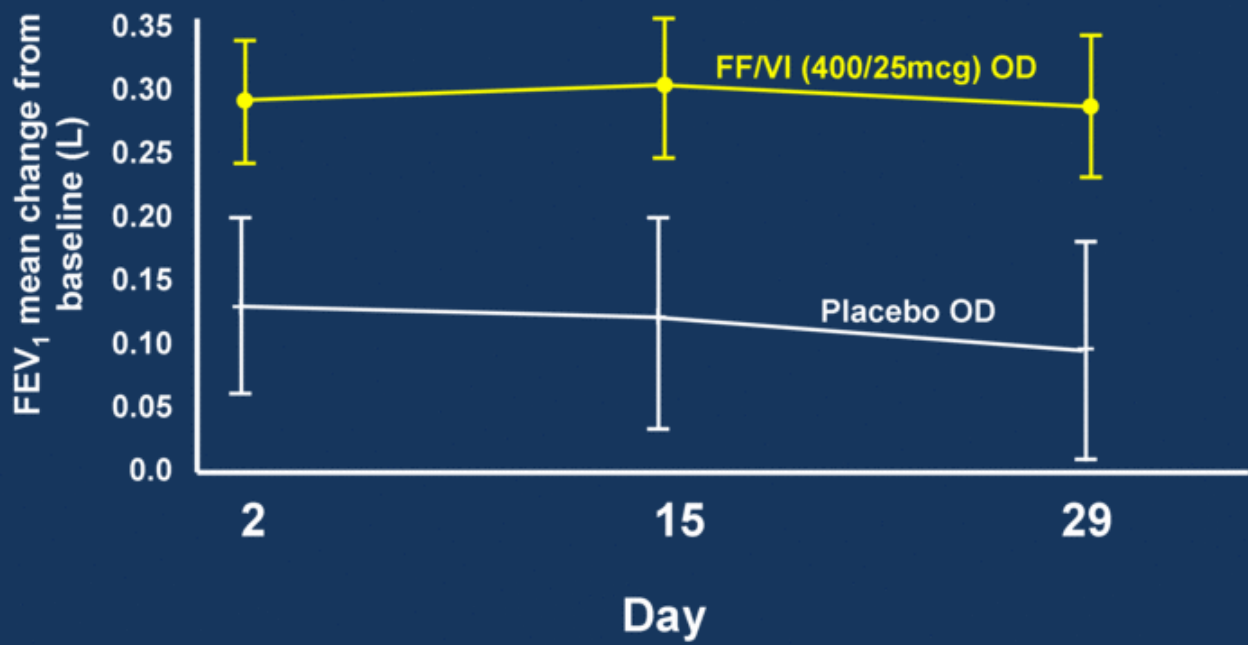
Time course of FEV₁: Day 1



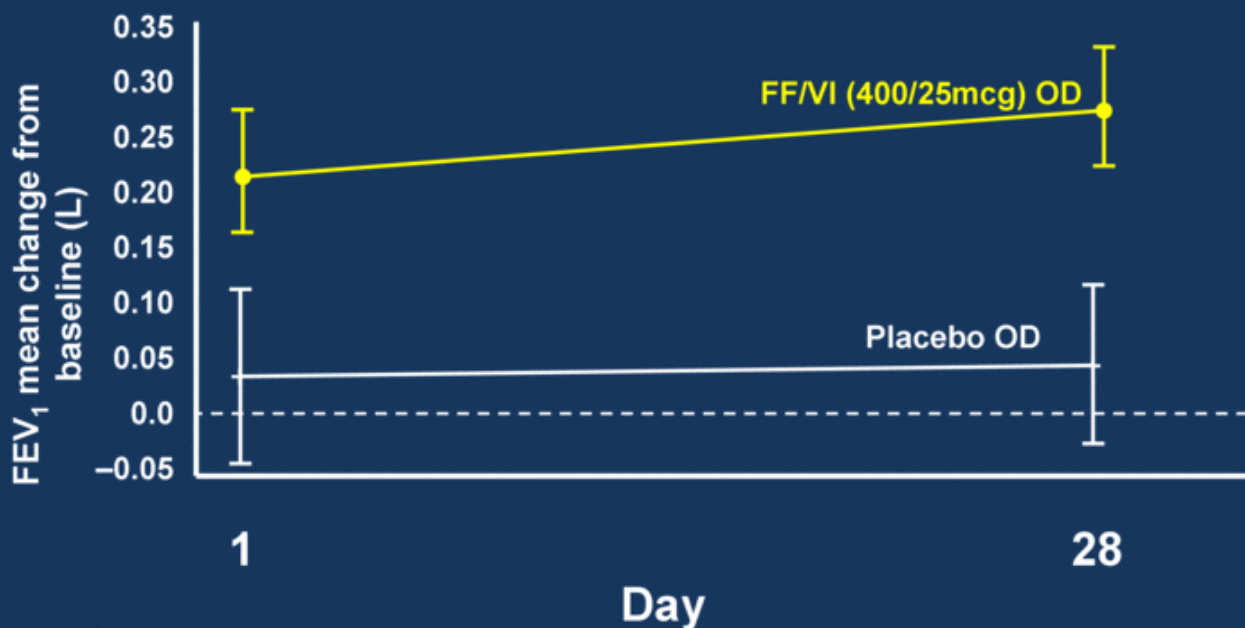
Time course of FEV₁: Day 28



Δ trough FEV₁



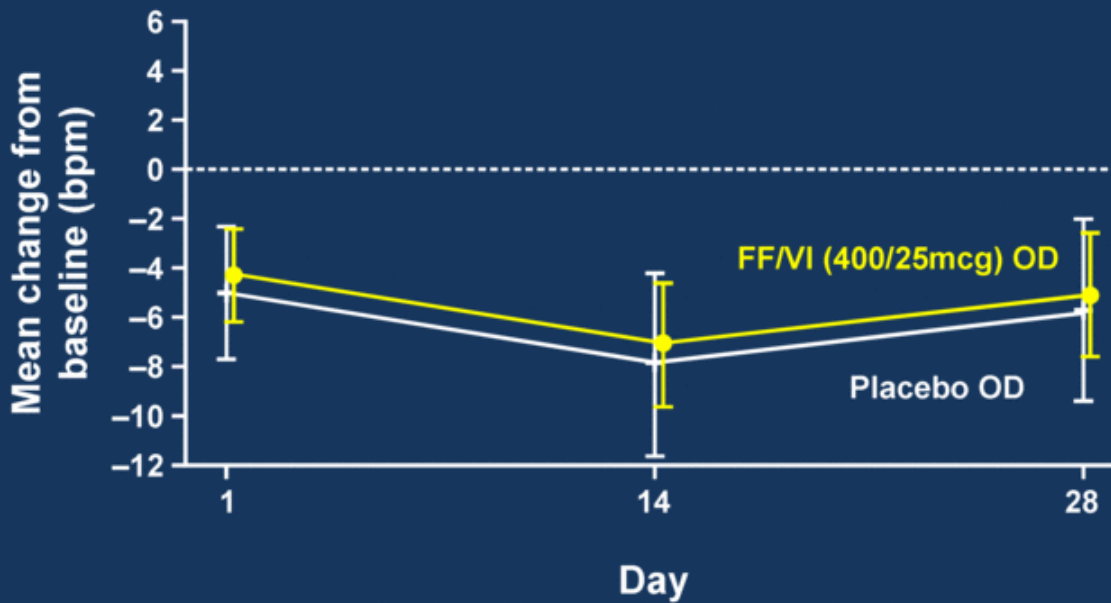
Adjusted mean change from baseline in weighted mean FEV₁



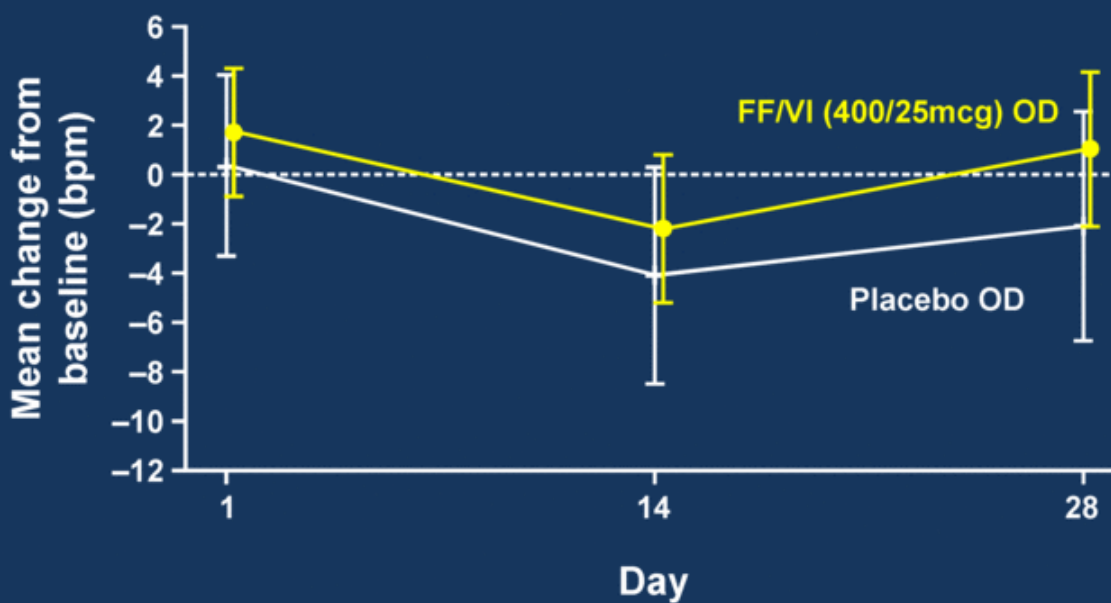
Common adverse events (>1 patient)

n (%)	Placebo (N=20)	FF/VI (400/25mcg) OD (N=40)
Any event	10 (50)	27 (68)
Nasopharyngitis	3 (15)	7 (18)
Headache	1 (5)	6 (15)
Oral candidiasis	0 (0)	3 (8)
Dizziness	1 (5)	2 (5)
Chest Pain	1 (5)	1 (3)
Dysphonia	0 (0)	2 (5)

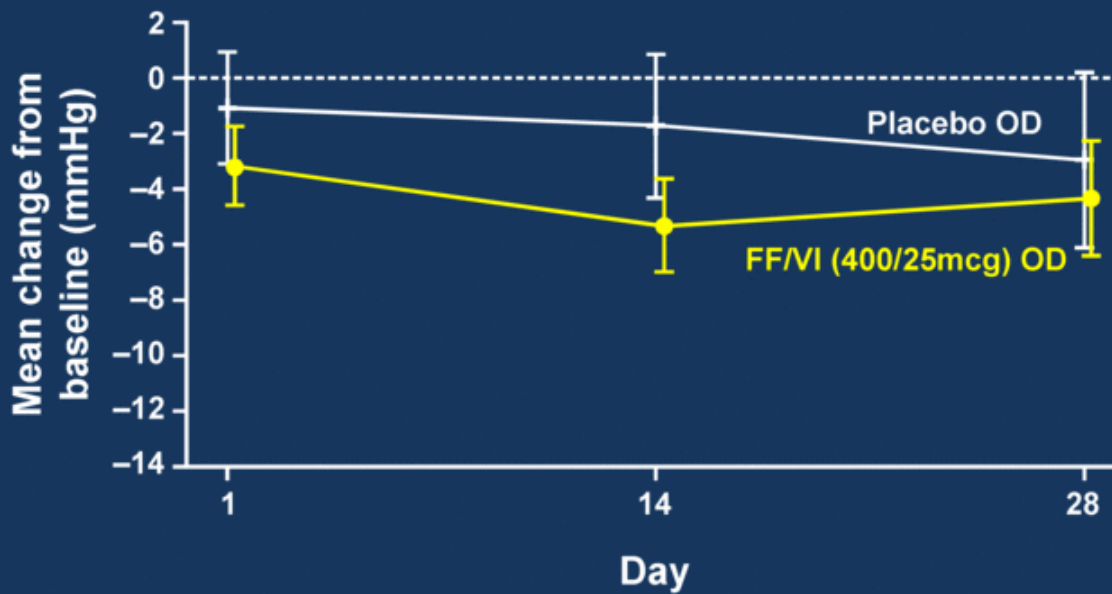
Adjusted mean change from baseline in weighted mean heart rate



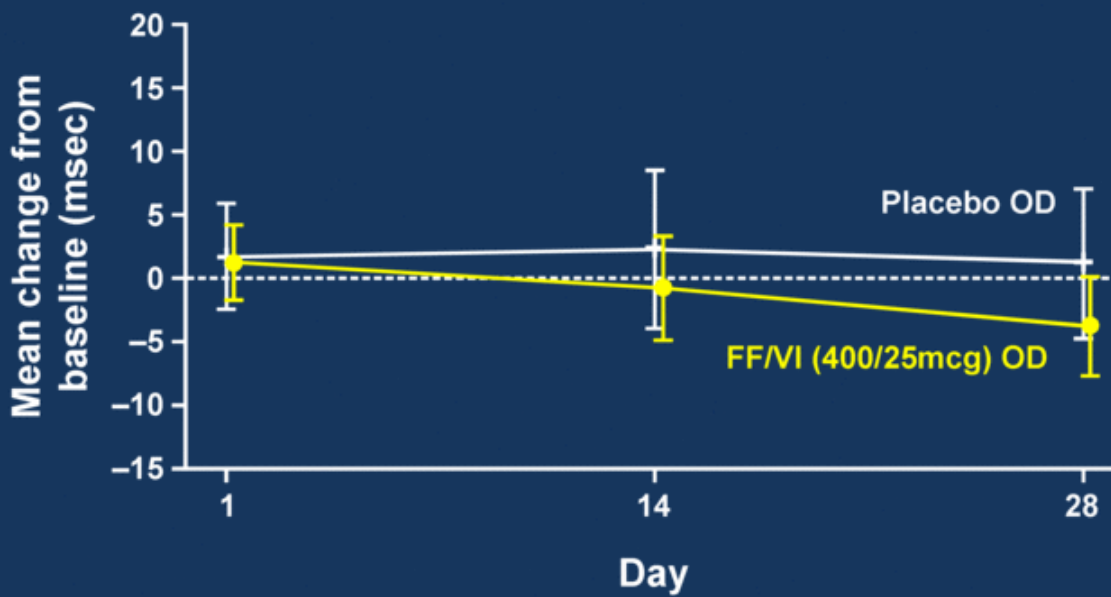
Adjusted mean change from baseline in maximum heart rate



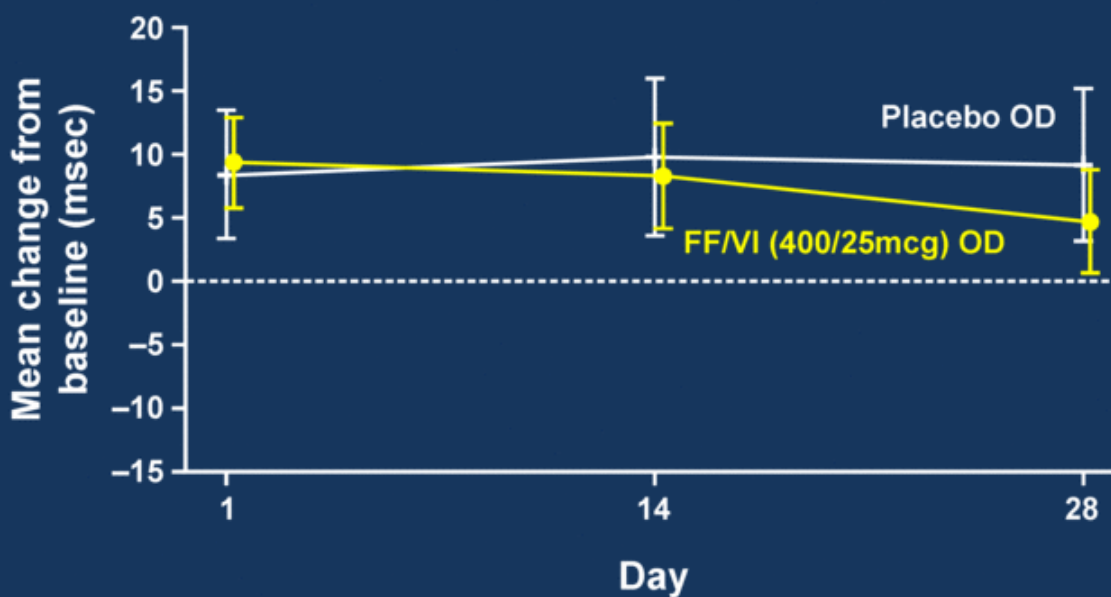
Adjusted mean change from baseline in weighted mean diastolic BP



Adjusted mean change from baseline in weighted mean QTcF



Adjusted mean change from baseline in maximum QTcF



Summary

- **FF/VI** demonstrated a clear improvement in 24h trough and serial FEV₁
- **FF/VI** was well tolerated over the 28-day treatment period
- **FF/VI** showed no adverse impact on HR or other vital signs
- **FF/VI** demonstrated no clinically relevant impact on QTc

Conclusions

- **FF/VI** is well tolerated and induces improvements in lung function in patients with COPD
- **FF/VI** may function as a once-daily combination therapy in COPD

24h duration of the novel long-acting β_2 agonist vilanterol trifenate in uncontrolled asthma

Lötvall J¹, Bateman ED², Bleecker ER³, Busse W⁴,
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⁴Department of Medicine, University of Wisconsin, Madison, WI, USA

⁵School of Translational Medicine, University of Manchester, Manchester, UK

⁶Respiratory Medicine Development Centre, GlaxoSmithKline, London, UK

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Acknowledgements

- **Funded by GlaxoSmithKline**
- **Editorial support by Gardiner-Caldwell Communications, funded by GlaxoSmithKline**
- **Study management: Suus Baggen (GlaxoSmithKline)**
- **Investigators and staff 88 centres**

Background

- Adding a LABA to ICS improves asthma control
- Current ICS/LABA therapies are indicated twice-daily
- ICS/LABA therapies can be further improved
- Adherence may improve with once daily treatment
- Vilanterol trifenate (VI)
 - Novel, inhaled LABA
 - Inherent 24h activity
 - Clinical efficacy not previously presented
 - In development as combination therapy
 - Asthma
 - COPD

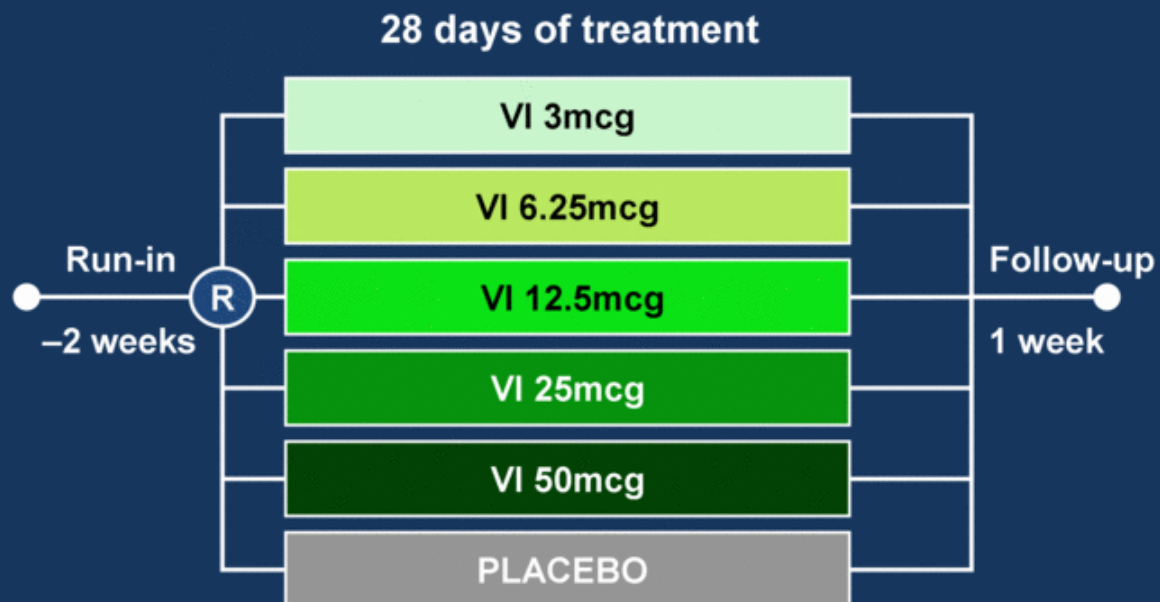
Study objectives

- To evaluate VI in asthma
 - Dose response
 - Clinical efficacy
 - Safety

 - Five doses of VI / Placebo
 - Dosing in evening
 - Persistent asthma
 - Regular treatment ICS

Study design

- Multicentre, randomised, double-blind, placebo-controlled, parallel-group, dose-ranging study
- Endpoints
 - primary: Δ trough FEV₁ Day 28
 - secondary:
 - Mean 24h FEV₁
 - Symptom-free days
 - Safety and tolerability

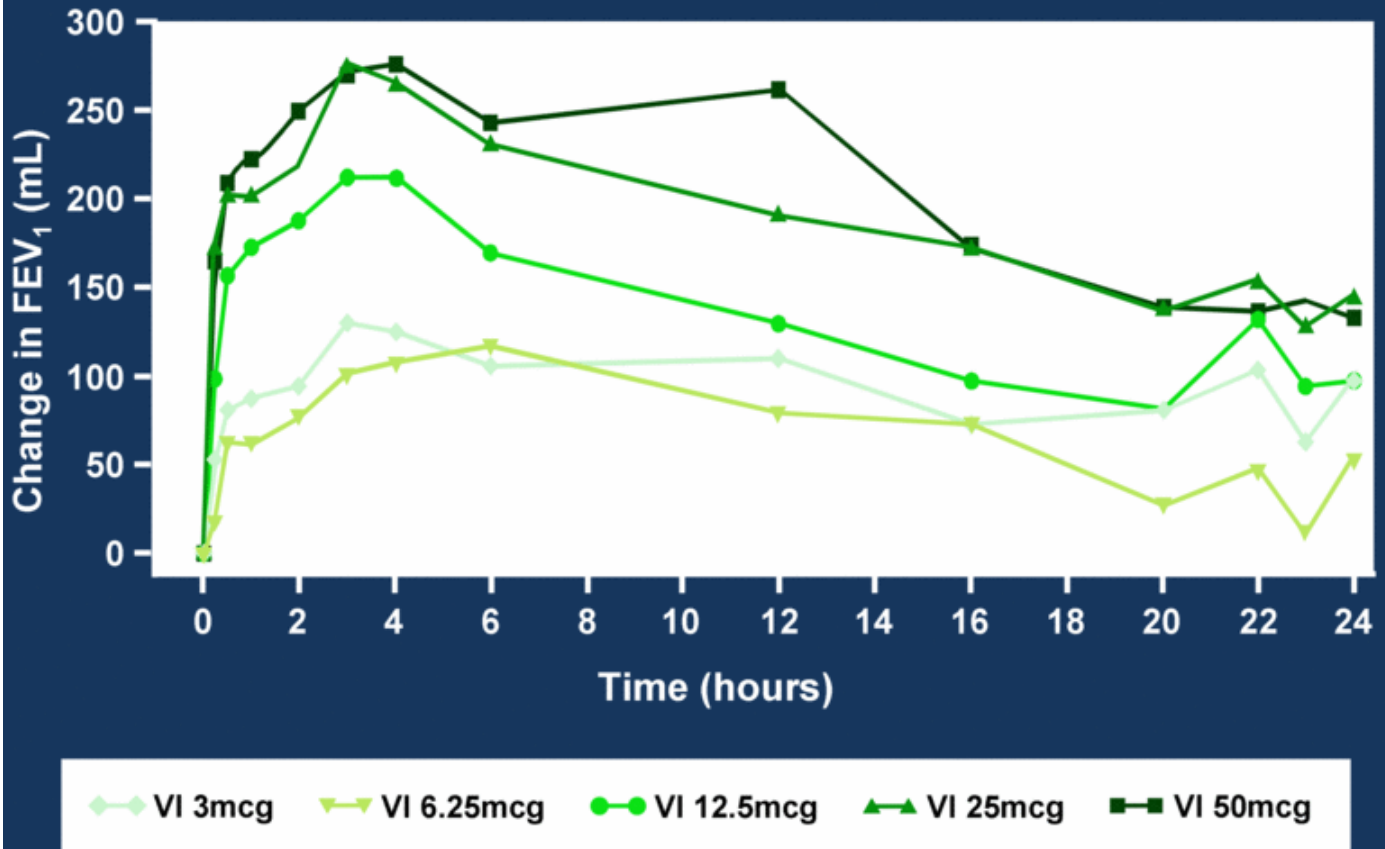


- ≥ 12 years of age at Visit 1
- History of persistent asthma
- FEV_1 reversibility $\geq 12\%$ and ≥ 200 mL
- Maintenance ICS
- Pre-bronchodilator FEV_1 between ≥ 40 and $\leq 90\%$ predicted at Visit 1

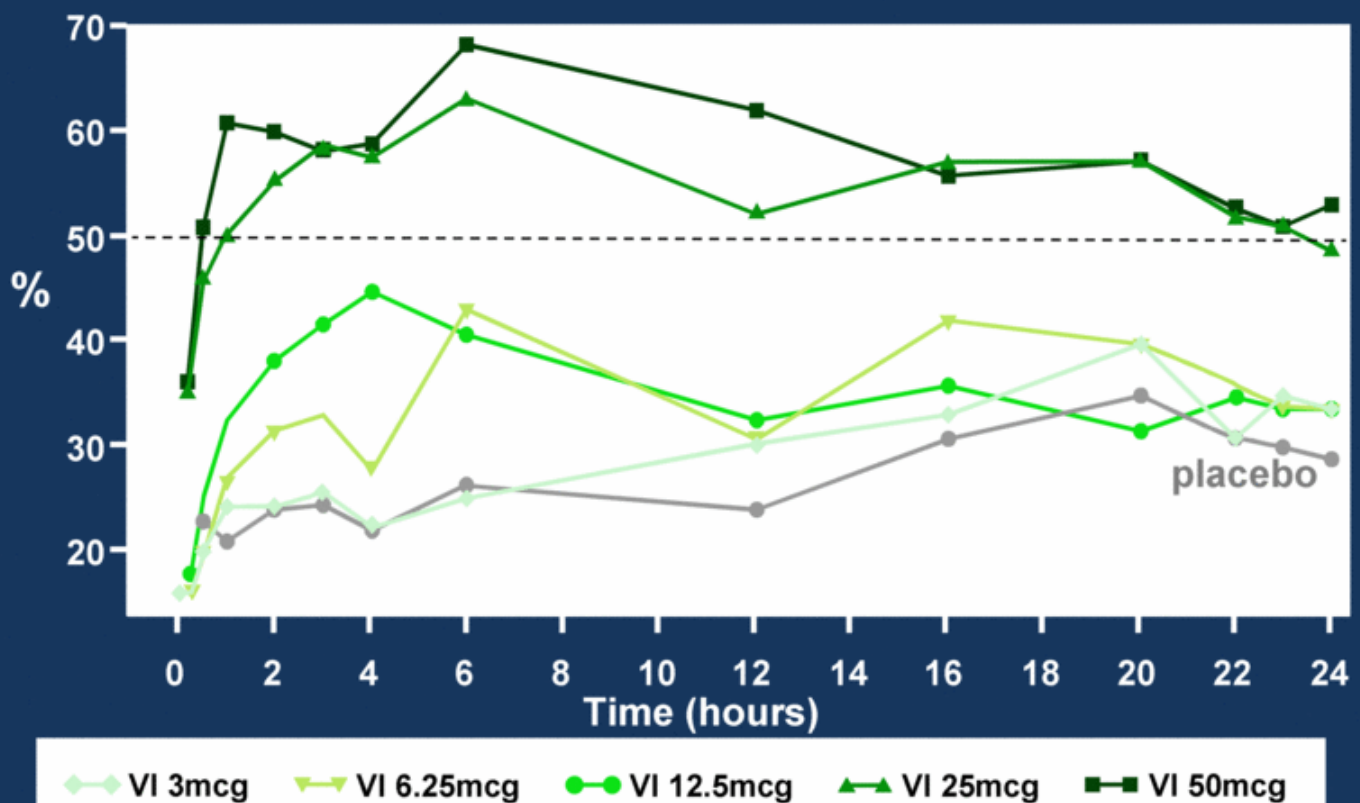
Patient demographics

- Across treatment groups
 - Mean age 40-44 years;
 - 50–60% female
- Screening lung function
 - Mean pre-bronchodilator FEV_1 : 2.1–2.3L (65–68%)
 - Mean reversibility: 24–27%

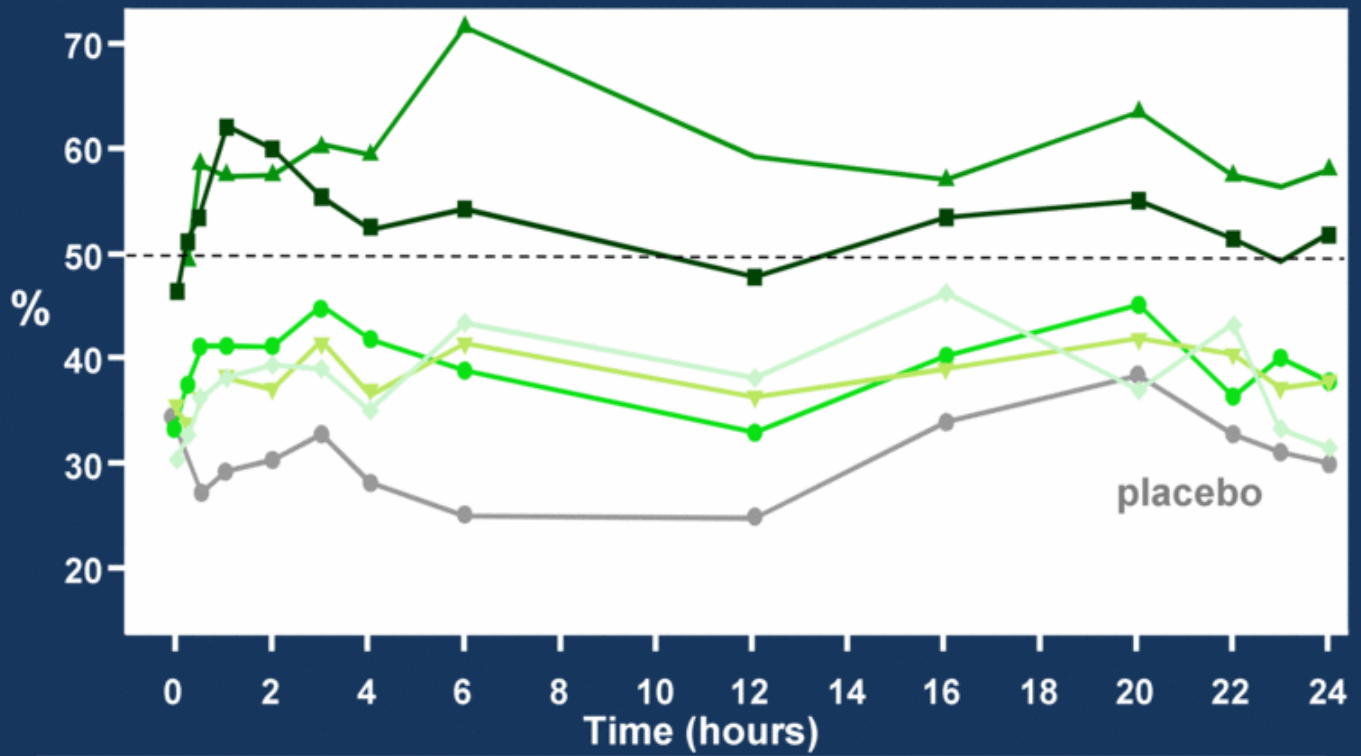
Time course of FEV₁: Day 1 (difference from placebo)



Proportion of patients with Δ FEV₁ \geq 200mL & \geq 12%: Day 1

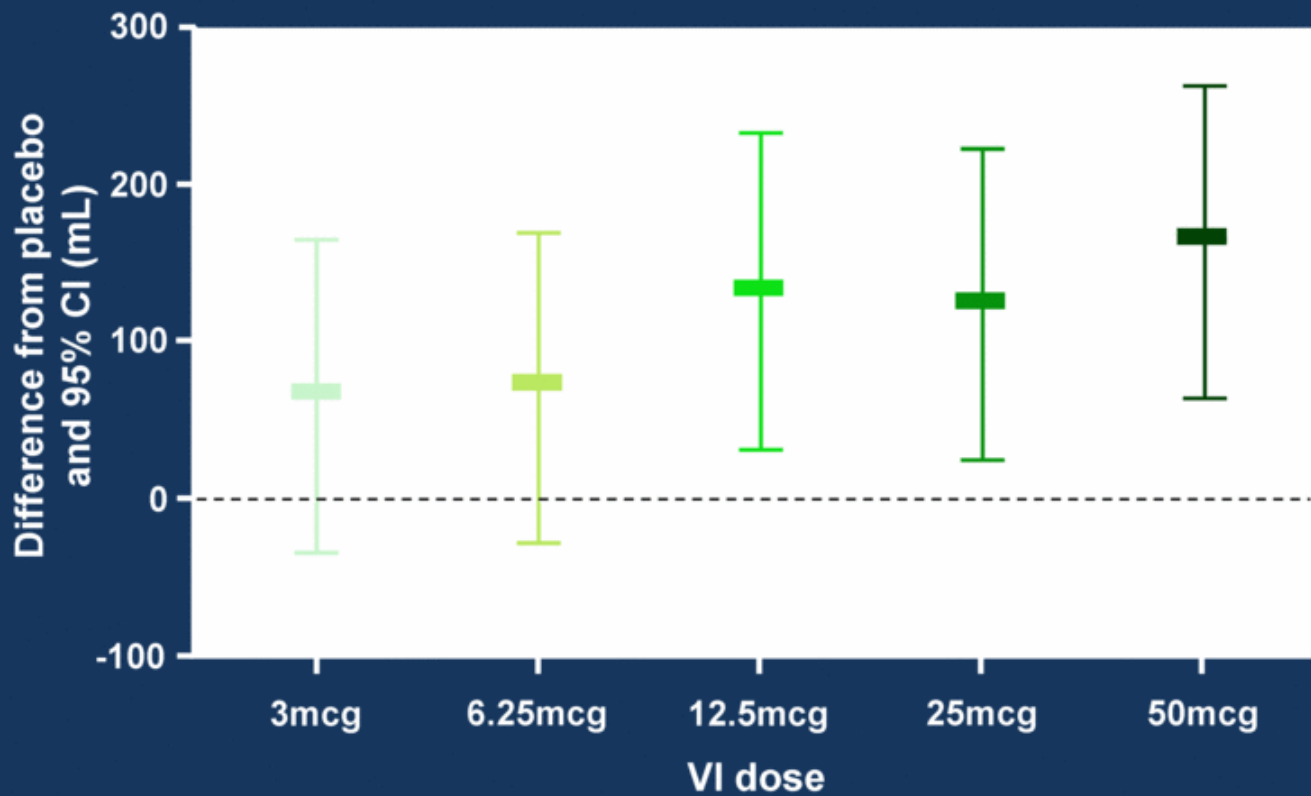


Proportion of patients with Δ FEV1 \geq 200mL & \geq 12%: Day 28

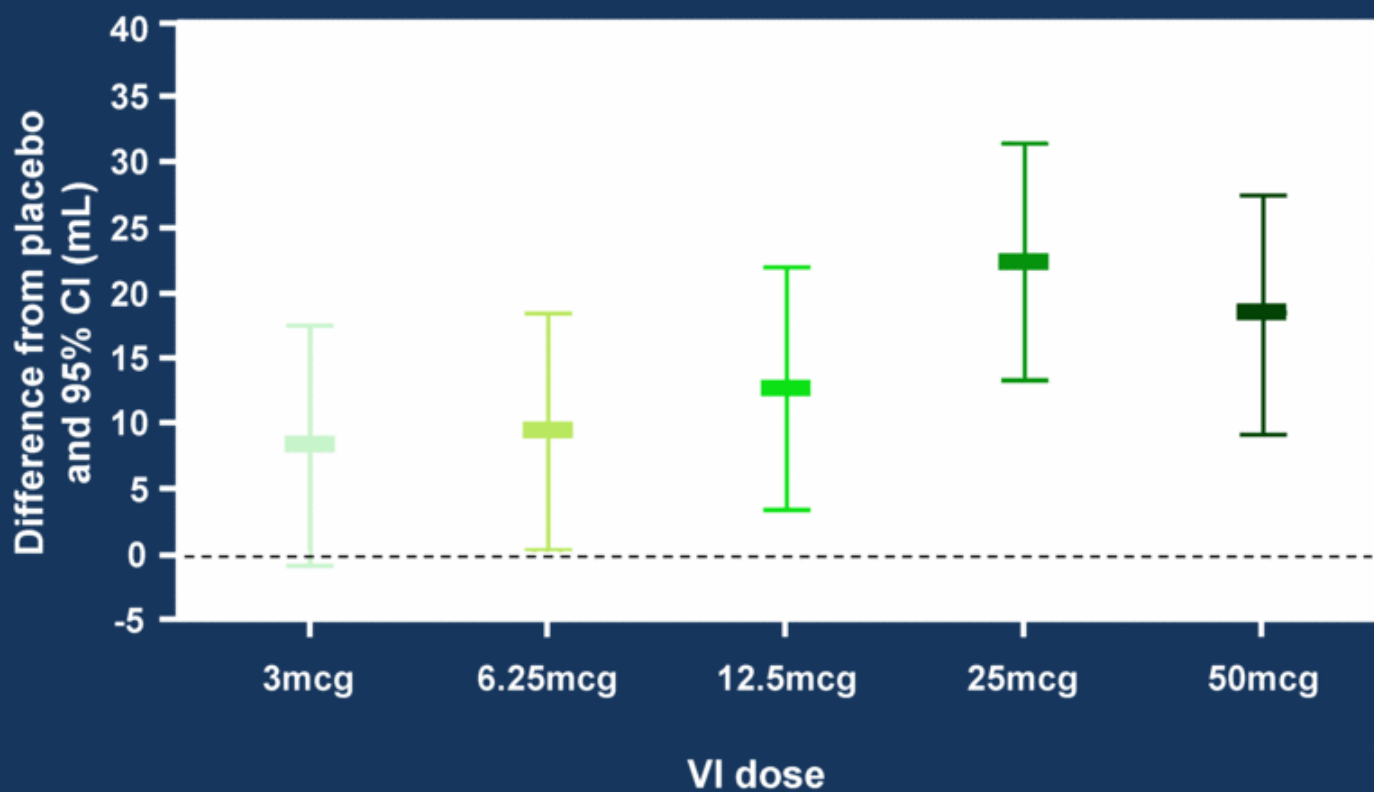


◆ VI 3mcg ▼ VI 6.25mcg ● VI 12.5mcg ▲ VI 25mcg ■ VI 50mcg

Change in baseline trough FEV₁ day 28



Percentage of symptom-free 24h periods



LABA-class associated AEs

- Headache (all groups) 7–12% VI, 8% placebo
- Tremor: 2 patients (6.25mcg)
- ↓ Glucose tolerance (1 patient 12.5mcg)
- ↑ Blood glucose levels: 1 patient (50mcg VI; unrelated to treatment)
- No AEs of low potassium reported
- No dose-dependent increases in AEs
- No serious AEs reported in any group
- No effect observed on QTcf

Conclusions

- In patients receiving maintenance ICS, VI:
 - FEV₁ duration of ≥24h at dose ≥12.5mcg
 - Beneficial therapeutic ratio at 12.5mcg - 50mcg
 - Optimal dose: 25mcg
 - Is well tolerated
- Developed as a once-daily ICS/LABA combination therapy for asthma/COPD

