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): **May 20, 2013**

THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**000-30319**	**94-3265960**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On May 20, 2013 at the American Thoracic Society International Conference in Philadelphia, Pennsylvania, GlaxoSmithKline plc (GSK) presented posters containing information from Phase 3b studies of the combination treatment fluticasone furoate/vilanterol (FF/VI) and a Phase 3 study of the combination treatment umeclidinium bromide (UMEC)/VI. FF/VI, known in the United States as BREO™ ELLIPTA™ (100/25mcg), recently gained U.S. Food and Drug Administration approval as an inhaled long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. It is not indicated for the relief of acute bronchospasm or the treatment of asthma. FF/VI remains in development elsewhere in the world for the maintenance treatment of asthma and COPD, with pending marketing authorization applications in a number of countries. It is not currently approved or licensed in the European Union or anywhere outside of the U.S. UMEC, a long-acting muscarinic antagonist, combined with VI, a LABA, is a once-daily investigational medicine for the maintenance treatment of patients with COPD. FF/VI and UMEC/VI are in development under the LABA collaboration agreement between GSK and Theravance, Inc. The posters are filed as Exhibits 99.1 to 99.2 to this report and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	**Description**
Exhibit 99.1	Once-daily (OD) fluticasone furoate/vilanterol 100/25mcg (FF/VI) compared with twice-daily (BD) fluticasone propionate/salmeterol 250/50mcg (FSC) in patients with COPD

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: May 20, 3013

By: /s/ **Michael W. Aguiar**
Michael W. Aguiar
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
Exhibit 99.1	Once-daily (OD) fluticasone furoate/vilanterol 100/25mcg (FF/VI) compared with twice-daily (BD) fluticasone propionate/salmeterol 250/50mcg (FSC) in patients with COPD
Exhibit 99.2	Efficacy and safety of once-daily umeclidinium/vilanterol 125/25mcg in patients with COPD

POSTER NO. 806

Once-daily (OD) fluticasone furoate/vilanterol 100/25mcg (FF/VI) compared with twice-daily (BD) fluticasone propionate/salmeterol 250/50mcg (FSC) in patients with COPD

Dransfield M(1), Crim C(2), Feldman G(3), Korenblat P(4), LaForce C(5), Locantore N(2), Pistolesi M(6), Watkins M(2), Martinez F(7)

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INTRODUCTION

· Currently available ICS/LABA combinations for moderate/severe COPD require twice-daily dosing.

· FF and VI are, respectively, a novel ICS and LABA in development as a once-daily combination therapy (FF/VI) for COPD and asthma.

OBJECTIVES

· To compare the efficacy and safety profiles of once-daily FF/VI 100/25mcg with twice-daily FSC (250/50mcg) in patients with moderate/severe COPD.

METHODS

· Two randomized, double-blind, double-dummy, multi-center parallel-group studies (HZC109 [Study 1] and HZC352 [Study 2]), of 12 weeks duration, were identical in design, conduct and analysis.

· Patients (≥40 years of age, ≥10 pack-years smoking history, post-bronchodilator FEV_1 ≤70%, FEV_1/FVC ratio ≤0.70 at screening, no requirement of prior exacerbations) completed a 2-week placebo run-in and were randomized 1:1 to once-daily (morning) FF/VI 100/25 via the ELLIPTA™ two-strip dry powder inhaler, or twice-daily FSC 250/50 via DISKUS™.

· Primary endpoint was change from baseline in weighted mean (wm) 0–24h FEV_1 on Day 84. Secondary endpoint was time to onset on Day 1. Safety was assessed throughout the study.

· Outcomes of the individual studies and pooled data are presented. A step-down statistical hierarchy was applied to analysis of the individual studies but not the pooled data. In Study 1 and Study 2, a statistically significant ($p<0.05$) treatment difference on the primary endpoint was required for statistical inference to be drawn on subsequent endpoints.

RESULTS

· 1030 patients (Study 1: 519; Study 2: 511) were randomized and received at least one dose of study medication (intent-to-treat [ITT] population). 950 completed the studies. On-treatment withdrawal rates were 8% in both treatment arms.

· Patient demographics were well matched (Table 1).

Table 1. Patient demographics and screening characteristics (pooled data, ITT population)

	FF/VI 100/25 N=519	FSC 250/50 N=511
Age, years	61.3 (8.8)	61.5 (8.7)
Male sex, n (%)	345 (66)	336 (66)
BMI, kg/m^2	27.4 (5.9)	27.4 (5.7)
Smoking pack years	40.7 (21.2)	41.6 (24.1)
Post-bronchodilator FEV_1, L	1.47 (0.50)	1.45 (0.47)
% predicted post-bronchodilator FEV_1	48.3 (11.9)	48.0 (12.0)
% reversibility FEV_1	11.2 (13.4)	11.9 (13.4)
Post-bronchodilator FEV_1/FVC, L	0.50 (0.10)	0.50 (0.10)

Values are mean (SD) unless otherwise stated

Efficacy: primary endpoint

· Change from baseline in 0–24h wmFEV_1 on Day 84 was significantly ($p<0.001$) greater with FF/VI than with FSC in Study 1 and in the pooled analysis, but not in Study 2 (Table 2).

· An overall pattern of greater lung function over 24h on Day 84 was observed with FF/VI compared with FSC (Figure 1).

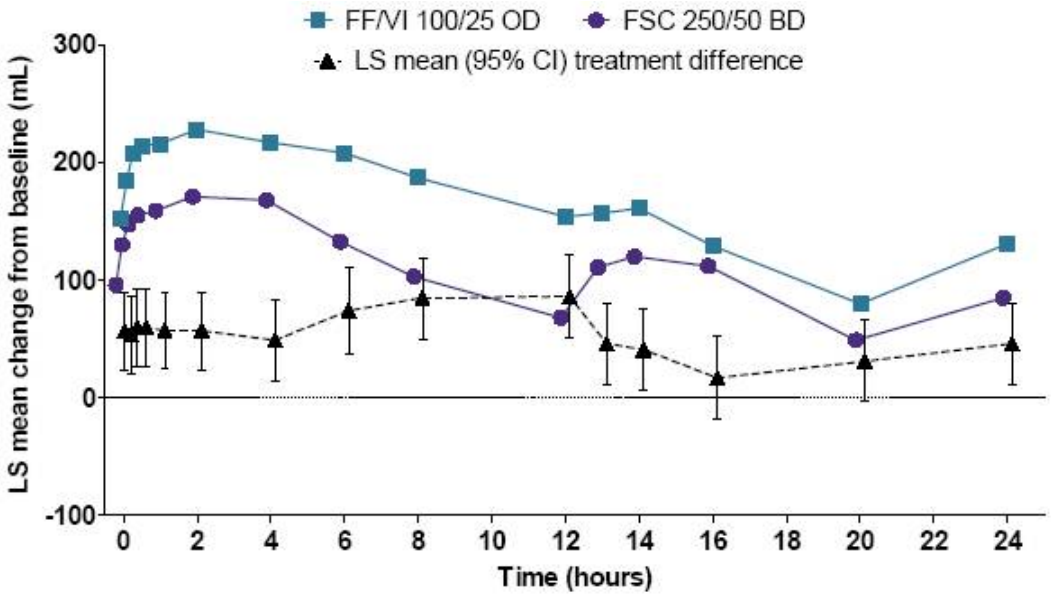
Table 2. Change from baseline 0–24h wmFEV_1 (mL) after 12 weeks (Study 1, Study 2 & pooled, ITT population)

	FF/VI 100/25	FSC 250/50	Treatment diff

			(95% CI)
Pooled	n=447 158 (12)	n=430 104 (12)	54 (21, 88) p=0.001
Study 1	n=228 174 (15)	n=213 94 (16)	80 (37, 124) p<0.001
Study 2	n=219 142 (18)	n=217 114 (18)	29 (–22, 80) p=0.267

Values are least squares mean (SD) unless otherwise stated

Figure 1. LS mean FEV_1 change from baseline over 24h, Day 84 (pooled data, ITT population)



CI=confidence interval; LS=least squares

Efficacy: secondary endpoint

· Median time to ≥100mL increase from baseline FEV_1 was significantly faster with FF/VI (15–16min) than FSC (30min) in Study 1 (p=0.012) and in the pooled analysis (p=0.026) (Figure 2), but significance could not be inferred for Study 2 (FF/VI: 16min, FSC: 30min).

Figure 2. Cumulative % of patients achieving ≥100mL increase from baseline FEV_1, Day 1 (pooled data, ITT population)

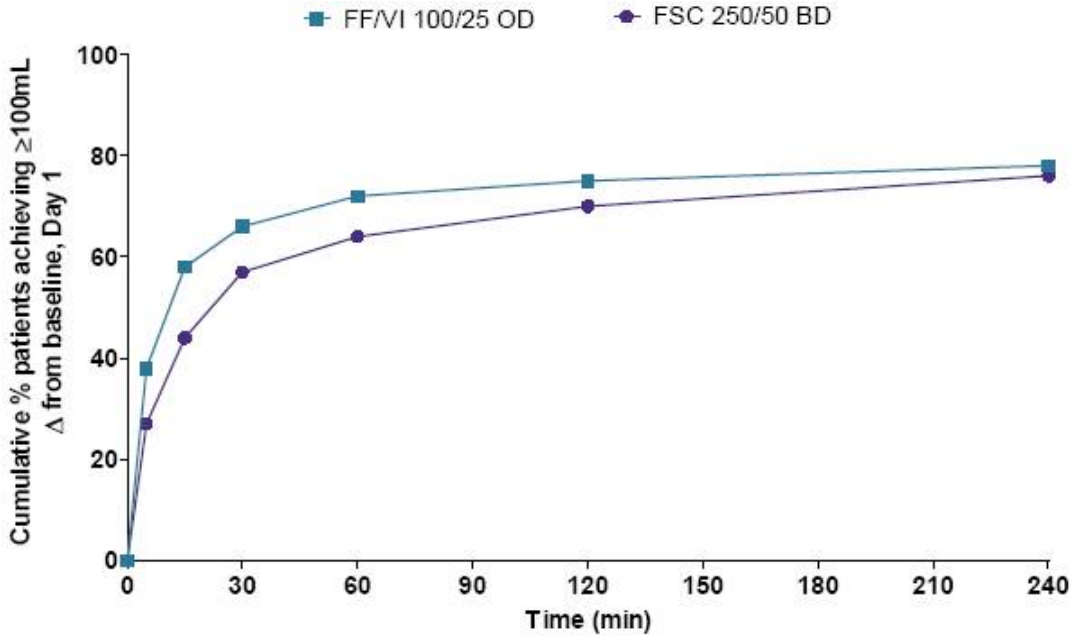


Table 3. Summary of on-treatment AEs by treatment group (pooled data, ITT population)

	FF/VI 100/25 N=519	FSC 250/50 N=511
Any AE	118 (23)	125 (24)
Headache	28 (5)	21 (4)
Nasopharyngitis	14 (3)	12 (2)
Any SAE	8 (2)	11 (2)

AEs occurring in ≥3% of patients in either treatment group shown
AE=adverse event, SAE=serious adverse event

Safety

- AE frequency was similar between treatment groups (Table 3).

- No abnormalities of clinical concern were observed in either study for laboratory values, including urinary cortisol, or ECG readings.

- A statistically significant treatment difference (FF/VI - FSC) in 0–4h weighted mean pulse rate (95% CI) of –1.9bpm (–3.3, –0.5) was observed at Week 12 in Study 1; this difference was not considered to be clinically significant. No difference in weighted mean pulse rate was observed between FF/VI and FSC in Study 2.

CONCLUSIONS

- Pooled analysis of these two replicate studies found once-daily FF/VI 100/25 to produce a greater improvement in 24h lung function than twice-daily FSC 250/50 after 12 weeks of treatment.

- FF/VI confers a more rapid improvement in lung function than FSC in the first hour of dosing on Day 1.

- No baseline factors that may explain the differential outcomes of Study 1 and Study 2 were apparent.

- No substantial safety concerns were identified in relation to FF/VI. Both treatments were well tolerated overall with similar safety profiles.

ACKNOWLEDGMENTS

- The presenting author, Mark Dransfield, declares the following real or perceived conflicts of interest during the last 3 years in relation to this presentation: has served as a consultant for Boehringer Ingelheim (BI), GlaxoSmithKline (GSK) and Ikaria. He has received grant funding from the NHLBI for COPD-related research and contracted research funding from Aeris, AstraZeneca, BI, Boston Scientific, Centocor, Forrest, GSK, Ikaria, MedImmune, Otsuka and Pfizer.
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Presented at the American Thoracic Society Annual Congress, Philadelphia, PA, USA, 17–22 May 2013

Poster No. 39941

Efficacy and safety of once-daily umeclidinium/vilanterol 125/25mcg in patients with COPD

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INTRODUCTION

· Current guidelines recommend treatment with one or more long-acting bronchodilators for patients with moderate-to-very severe chronic obstructive pulmonary disease (COPD).(1),(2)

· Umeclidinium (UMEC)/vilanterol (VI) is a novel long-acting muscarinic antagonist (LAMA)/long-acting β_2-agonist (LABA) combination bronchodilator in development for the maintenance treatment of COPD.

OBJECTIVES

· To evaluate the efficacy and safety of once-daily UMEC/VI 125/25 mcg compared with its components (UMEC and VI) and placebo in patients with COPD.

METHODS

Study design and treatment

· Multicenter, randomized, double-blind, placebo-controlled, parallel-group study (ClinicalTrials.gov: NCT01313637; protocol number: DB2113361).

· Key eligibility criteria: ≥40 years of age; clinically established history of COPD; current or former cigarette smokers with ≥10-pack-year smoking history; post-albuterol forced expiratory volume in 1 second (FEV_1)/forced vital capacity (FVC) <0.7 and predicted FEV_1 ≤70%; and a mMRC dyspnea scale score ≥2.

· Following a 7 to 14 day run-in, patients were randomized 3:3:3:2 to 24 weeks treatment with UMEC/VI 125/25mcg, UMEC 125mcg, VI 25mcg or placebo once-daily via the ELLIPTA™ dry powder inhaler. Concurrent use of inhaled corticosteroids (ICS) and rescue albuterol was allowed.

· All patients were required to provide written informed consent prior to study participation. The study was conducted in accordance with the declaration of Helsinki, Good Clinical Practice guidelines, and IRB approval was obtained.

Endpoints

· *Primary efficacy:* trough FEV_1 on Day 169 defined as the mean of the FEV_1 values obtained 23 and 24 hours after dosing on treatment Day 168.

· *Additional efficacy* included: 0–6h post-dose weighted mean (WM) FEV_1; transition dyspnea index (TDI) focal score; St George's Respiratory Questionnaire (SGRQ) score; rescue albuterol use; and time to first COPD exacerbation.

· *Safety*: adverse events (AEs); vital signs; 12-lead ECG and 24-h Holter electrocardiography (ECG); and clinical chemistry and hematology.

· Plasma pharmacokinetics (PK) were analyzed using population PK methodology.

RESULTS

Patient demographics and baseline characteristics

· A total of 2114 patients were enrolled; 1489 were included in the intention-to-treat (ITT) population (i.e., randomized and received at least one dose of study medication).

· Patient demographics and baseline characteristics were similar across treatment groups (Table 1). ICS use was similar across active treatment groups (44–47%) and placebo (50%).

TABLE 1. PATIENT DEMOGRAPHICS AND BASELINE CHARACTERISTICS

	Placebo N=275	UMEC 125 N=407	VI 25 N=404	UMEC/VI 125/25 N=403
Age, years	62.2 (8.53)	63.1 (8.48)	62.8 (8.8)	63.4 (8.08)
Sex, n (%)				
Male	175 (64)	270 (66)	265 (66)	264 (66)
Race, n (%)				

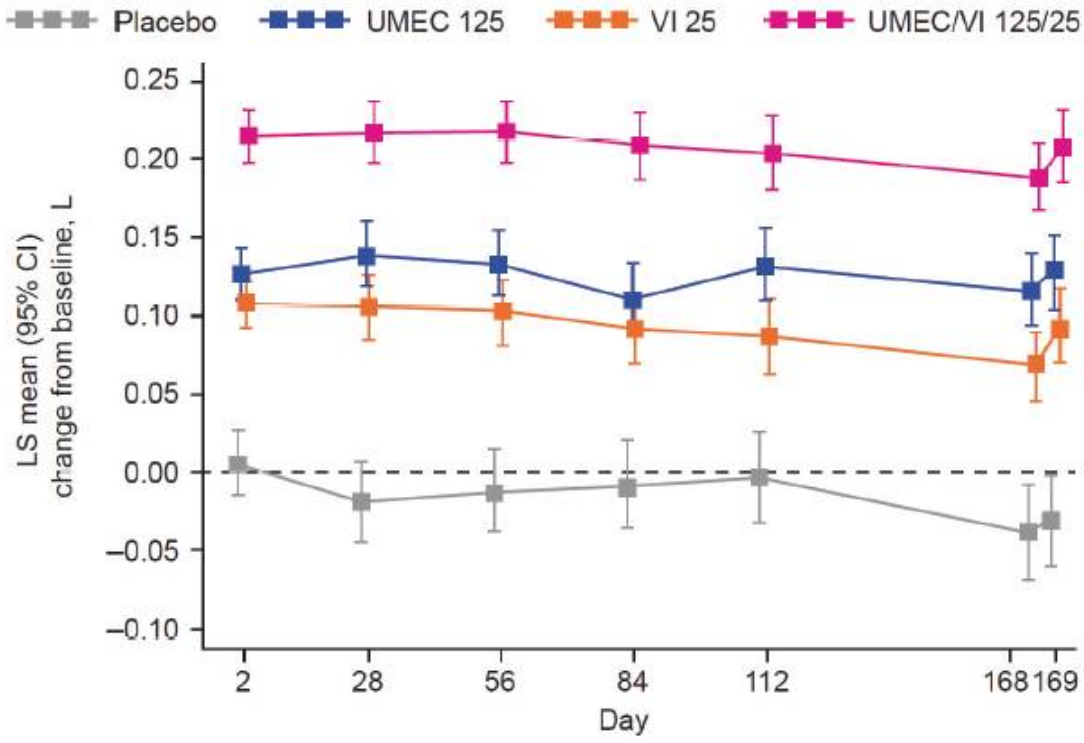
White	238 (87)	363 (89)	354 (88)	359 (89)
Patients with cardiovascular risk factors, n (%)(a)	150 (55)	220 (54)	236 (58)	233 (58)
Post-albuterol % predicted FEV_1	47.6 (12.47)	48.8 (12.32)	48.5 (12.74)	47.7 (12.53)
Post albuterol FEV_1, L	1.402 (0.4693)	1.457 (0.5034)	1.436 (0.5071)	1.414 (0.4836)
Post albuterol FEV_1/FVC	46.430 (11.3018)	46.972 (10.5943)	47.084 (11.1940)	45.905 (11.0383)
Patients reversible to albuterol(b), n (%)	77 (28)	132 (33)	119 (30)	133 (33)

Values are reported as mean (standard deviation) unless otherwise stated.
(a) Defined as current medical history of angina, myocardial infarction, stroke, diabetes, hypertension, or hyperlipidemia.
(b) Reversible was an increase in FEV_1 of $\geq$12% and $\geq$200 mL following administration of 4 puffs of albuterol.

Efficacy: Trough FEV_1

· Treatment with UMEC/VI 125/25 resulted in statistically significant improvements in trough FEV_1 at Day 169 *vs*. VI, UMEC 125 and placebo (p<0.001, Table 2). Comparisons at all other visits were statistically significant (p<0.001, Figure 1). All comparisons of UMEC 125 and VI *vs*. placebo were statistically significant (p<0.001).

FIGURE 1. TROUGH FEV_1 (ITT POPULATION)



Efficacy: additional endpoints

· Greater improvements in 0–6h post-dose WM FEV_1 were shown for UMEC/VI 125/25 *vs*. VI, UMEC 125 and placebo (p<0.001 for all comparisons at all visits, Figure 2 and Table 2). Both UMEC 125 and VI consistently improved 0–6h post-dose WM FEV_1 *vs*. placebo (p<0.001, Table 2).

· Greater improvements in TDI focal score, SGRQ score, and rescue albuterol use were shown with UMEC/VI 125/25 compared with placebo (Table 2).

· The incidence of COPD exacerbations was lower with UMEC/VI 125/25 (6%), UMEC 125 (8%) and VI (8%) compared with placebo (14%). Analysis of time to first exacerbation showed that patients on UMEC/VI 125/25 had a lower risk of exacerbation *vs*. placebo (hazard ratio: 0.4; 95% CI: 0.2, 0.6 [p<0.001]; corresponding to a risk reduction of 60%).

TABLE 2: EFFICACY ENDPOINT COMPARISONS

(ITT POPULATION)

	UMEC 125 (N=407)	**VI 25 (N=404)**	**UMEC/VI 125/25 (N=403)**
Trough FEV_1 at Day 169, L(a)			
Difference *vs*. placebo	0.160*	0.124*	0.238*

(95% CI)	(0.122,0.198)	(0.086,0.162)	(0.200,0.276)
UMEC/VI 125/25 *vs.* monotherapy	0.079*	0.114*	
(95% CI)	(0.046,0.112)	(0.081,0.148)	
0–6h post-dose WM FEV_1 at Day 168, L(a)			
Difference *vs.* placebo	0.178*	0.145*	0.287*
(95% CI)	(0.141, 0.216)	(0.107, 0.182)	(0.250, 0.324)
UMEC/VI 125/25 *vs.* monotherapy	0.109*	0.142*	
(95% CI)	(0.076, 0.141)	(0.109, 0.175)	
TDI focal score at Day 168(a)			
Difference *vs.* placebo	0.4	0.5	1.0*
(95% CI)	(-0.1, 0.9)	(0.0, 1.0)	0.5, 1.5
OR *vs.* placebo (95% CI)	1.7‡ (1.2, 2.4)	1.5‡ (1.0, 2.1)	2,5* (1.7, 3.5)
SGRQ score at Day 168			
Difference *vs.* placebo	-0.31	-0.87	-3.60*
(95% CI)	(-2.46, 1.85)	(-3.05, 1.30)	(-5.76, -1.44)
OR *vs.* placebo (95% CI)	1.2 (0.8, 1.7)	1.2 (0.9, 1.7)	1.7† (1.2, 2.4)
Rescue albuterol use at weeks 1–24, puffs/day			
Difference *vs.* placebo (95% CI)	-0.8* (-1.3, -0.4)	-0.8* (-1.2, 0.3)	-1.5* (-1.9, -1.0)

(a) Values are differences in least squares mean (95% CI); OR, odds ratio (based on proportion of responders according to outcome measure. *p≤0.001 vs placebo, † p≤0.005 vs placebo, ‡ p≤0.05 vs monotherapy. To account for multiplicity across treatment comparisons and endpoints, a step-down closed testing procedure was used.

Safety and pharmacokinetics

· Headache and nasopharyngitis were the most common AEs reported (Table 3).. The incidence of dry mouth was low (UMEC/VI 125/25 [2%] and ≤1% for UMEC 125, VI, and placebo).

· The incidence of SAEs was similar across treatment groups (5–6%). The most common SAE was COPD (<1–3%).

· Six deaths were reported (2 events of metastatic cancer in the UMEC 125 and VI groups; arteriosclerosis and pneumonia in placebo group; metastatic pancreatic carcinoma in UMEC 125 group; acute myocardial infarction in VI group).

· No clinically meaningful treatment-related changes in vital signs, ECG, or clinical laboratory parameters were observed for active treatments compared with placebo.

· There were no differences in the systemic exposure of UMEC 125 or VI when administered in combination or as monotherapy. In addition, patient demographics did not influence PK parameters of either compound.

FIGURE 2: 0–6h POST-DOSE WM FEV_1 (ITT POPULATION)

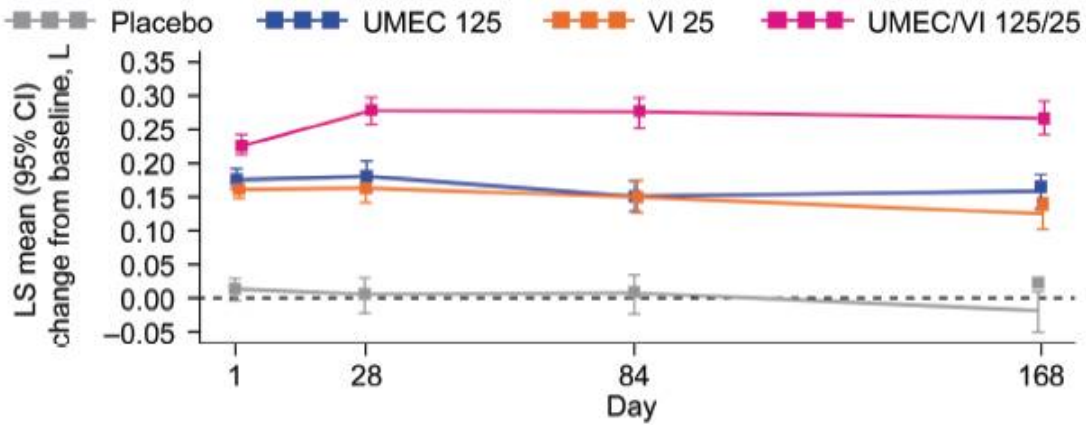


TABLE 3: OVERVIEW OF ADVERSE EVENTS

(ITT POPULATION)

	Placebo N=275	UMEC 125 N=407	VI 25 N=404	UMEC/VI 125/25 N=403
Any on-treatment AEs, n (%)	134 (49)	217 (53)	215 (53)	211 (52)
AEs reported by ≥3% patients, n (%)				
Nasopharyngitis	32 (12)	37 (9)	55 (14)	47 (12)
Headache	32 (12)	37 (9)	41 (10)	41 (10)
Cough	16 (6)	15 (4)	18 (4)	29 (7)
Back pain	13 (5)	17 (4)	10 (2)	10 (2)
Pyrexia	7 (3)	9 (2)	9 (2)	13 (3)
Hypertension	4 (1)	9 (2)	12 (3)	8 (2)
Toothache	7 (3)	12 (3)	10 (2)	4 (<1)
Arthralgia	5 (2)	5 (1)	8 (2)	11 (3)

Upper respiratory tract infection	7 (3)	6 (1)	9 (2)	7 (2)
Dyspnea	9 (3)	5 (1)	10 (2)	4 (<1)
Pain in extremity	5 (2)	8 (2)	12 (3)	3 (<1)
Chronic obstructive pulmonary disease	11 (4)	6 (1)	4 (<1)	6 (1)

CONCLUSIONS

- Once-daily dosing with UMEC/VI 125/25 improved lung function compared with the UMEC and VI monotherapies, and placebo in patients with COPD. Other assessments supported the efficacy of UMEC/VI 125/25.
- Safety and tolerability profiles of UMEC/VI 125/25 were similar to the monotherapies and placebo.
- This study supports the use of UMEC/VI 125/25 as a long-term maintenance treatment in COPD.

REFERENCES

(1) GOLD 2013. Available at: *http://www.Goldcopd.org/* Last accessed March 2013.
(2) Celli BR, Macnee W. *Eur Respir J* 2004; 23:932-946.

ACKNOWLEDGEMENTS

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