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): **November 13, 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 November 13, 2013 at the 18th Congress of the Asian Pacific Society of Respirology, Yokohama, Japan, GlaxoSmithKline plc ("GSK") presented an oral presentation on a Phase 3 study of the once-daily treatment combination of fluticasone furoate "FF", an inhaled corticosteroid, and vilanterol "VI", a long-acting beta$_2$ agonist, in Asian patients with chronic obstructive pulmonary disease (COPD). In addition, GSK presented a poster on an ethnic sensitivity assessment of FF/VI in asthma patients in Japan and Korea. In September 2013, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved FF/VI for the treatment of bronchial asthma (in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta$_2$ agonist is required). FF/VI is not indicated for the treatment of COPD in Japan. The MHLW has approved two doses of FF/VI - 100/25 mcg and 200/25 mcg. Both strengths will be administered once-daily using the ELLIPTA™, a new dry powder inhaler. RELVAR® ELLIPTA™ is the trade name in Japan. 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. FF/VI for the treatment of COPD is approved in the United States and Canada. FF/VI is not indicated for the relief of acute bronchospasm or the treatment of asthma in the United States or Canada. FF/VI is not approved or licensed anywhere outside of the United States, Japan and Canada. FF/VI is in development under the LABA collaboration agreement between Glaxo Group Limited and Theravance, Inc. The slide presentation and poster are filed as Exhibit 99.1 and 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	The efficacy and safety of inhaled fluticasone furoate (FF)/vilanterol (VI) in Asian patients with COPD
Exhibit 99.2	Ethnic sensitivity assessment of fluticasone furoate (FF)/vilanterol (VI) in asthma patients in Japan and Korea: a pre-specified subgroup analysis

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: November 13, 2013

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	The efficacy and safety of inhaled fluticasone furoate (FF)/vilanterol (VI) in Asian patients with COPD
99.2	Ethnic sensitivity assessment of fluticasone furoate (FF)/vilanterol (VI) in asthma patients in Japan and Korea: a pre-specified subgroup analysis

The efficacy and safety of inhaled fluticasone furoate (FF)/vilanterol (VI) in Asian patients with COPD

Jinping Zheng[1]; Teresita de Guia[2]; Jie Wang-Jairaj[3]; Amy H Newlands[3]; Changzheng Wang[4]; Chin-chou Wang[5]; Courtney Crim[6]; Nanshan Zhong[1]

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[6]GlaxoSmithKline, North Carolina, USA

STATEMENT OF INTEREST DISCLOSURE

Jinping Zheng has the following statement of interest

- served as a consultant for a local advisory board, and received lecture fees from AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Novartis, Takeda and Zambon

ACKNOWLEDGEMENTS

- Patients, investigators and staff at the 33 study centers in mainland China, Taiwan, the Philippines and South Korea
- Janet Flemming (data management); Eva Gomez and Farshid Hamayoun-Valiani (study management); Rehan Ali and QSI, Bangalore (data analysis and programming)
- Funded by GlaxoSmithKline (HZC113684; NCT01376245)
- Editorial support by Gardiner-Caldwell Communications, funded by GlaxoSmithKline

Background and objectives

- **Fluticasone furoate/vilanterol (FF/VI) combination**
  - Inhaled corticosteroid/long-acting beta$_2$-agonist
  - Once-daily combination treatment for COPD and asthma
  - Delivered via the ELLIPTA™ dry powder inhaler
  - 100/25mcg approved in the USA and Canada for COPD

- **Objectives**
  - To investigate efficacy and safety of three strengths of FF/VI in Asian COPD patients over 24 weeks
    - 50/25mcg; 100/25mcg; 200/25mcg
  - To evaluate suitability of FF/VI 100/25mcg as the therapeutic strength in Asian COPD patients

Study design

- **Placebo-controlled, double-blind, randomised, parallel-group, multicentre**

- **Study population**
  - Male or female Asian outpatients aged ≥40 years
  - Clinical diagnosis of COPD (ATS/ERS[1])
  - Current or prior smoking history of ≥10 pack-years
  - Post-salbutamol FEV_1/FVC ratio of ≤0.70
  - Post-salbutamol FEV_1 ≤70% of predicted
  - Modified Medical Research Council Dyspnoea Scale ≥2

[1]Celli BR, MacMee W. *Eur Respir J* 2004;23:932–46

Endpoints

- **Primary**
  - Change from baseline in trough FEV_1 at Week 24
- **Secondary**
  - Dyspnoea domain of CRQ-SAS[1,2] at Week 24
- **Other**
  - Daily diary card measures (COPD symptoms, albuterol use)
  - COPD Assessment Test™ (CAT)
- **Safety**
  - Adverse events including exacerbation and pneumonia
  - Clinical laboratory, vital signs and ECG
  - Change from baseline in urinary cortisol excretion

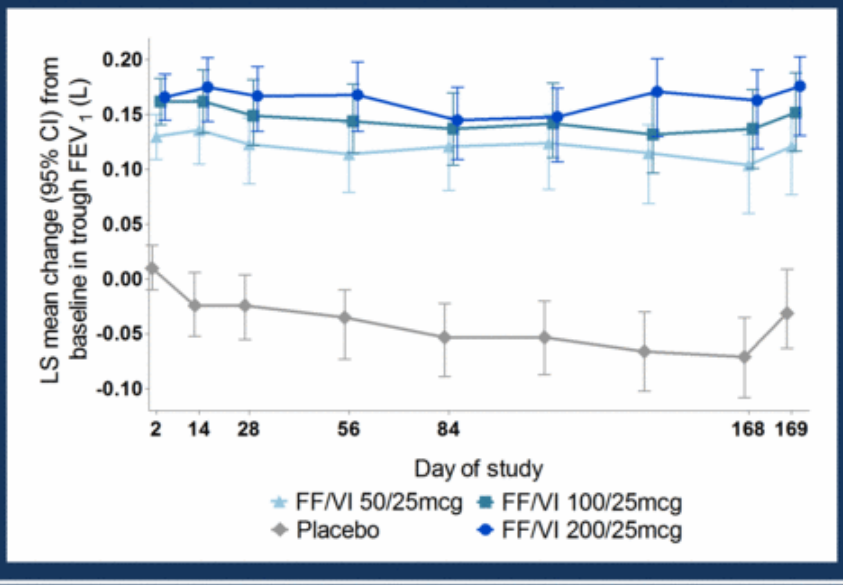
[1]Schünemann HJ. et al. *Chest* 2003;124:1421–9; [2]http://milo.mcmaster.ca/questionnaires/questionnaires

Baseline characteristics and demographics (ITT)

	FF/VI 50/25mcg (n=160)	FF/VI 100/25mcg (n=161)	FF/VI 200/25mcg (n=160)	Placebo (n=162)	Total (N=643)
Age, years[a]	65.2 (8.41)	65.1 (9.19)	62.7 (8.65)	64.7 (8.78)	64.4 (8.80)
Males, n (%)	144 (90)	149 (93)	145 (91)	146 (90)	584 (91)
Mean mMRC score[a]	2.2 (0.47)	2.2 (0.43)	2.3 (0.50)	2.3 (0.46)	2.2 (0.47)
Post-bronchodilator FEV_1 (L), *n*,[a,b]	*155* 1.16 (0.416)	*161* 1.22 (0.374)	*159* 1.21 (0.390)	*161* 1.18 (0.383)	*636* 1.20 (0.396)
Post-bronchodilator FEV_1 % predicted, *n*,[a,b]	*155* 47.5 (14.21)	*161* 49.6 (13.19)	*159* 48.2 (13.63)	*161* 48.6 (13.39)	*636* 48.5 (13.60)
Mean reversibility (%), *n*,[a,b]	*154* 14.1 (12.37)	*160* 12.8 (11.50)	*159* 15.2 (13.43)	*161* 12.8 (11.80)	*634* 13.7 (12.31)

[a]Mean (SD); [b]Recorded at Visit 1 (Screening)

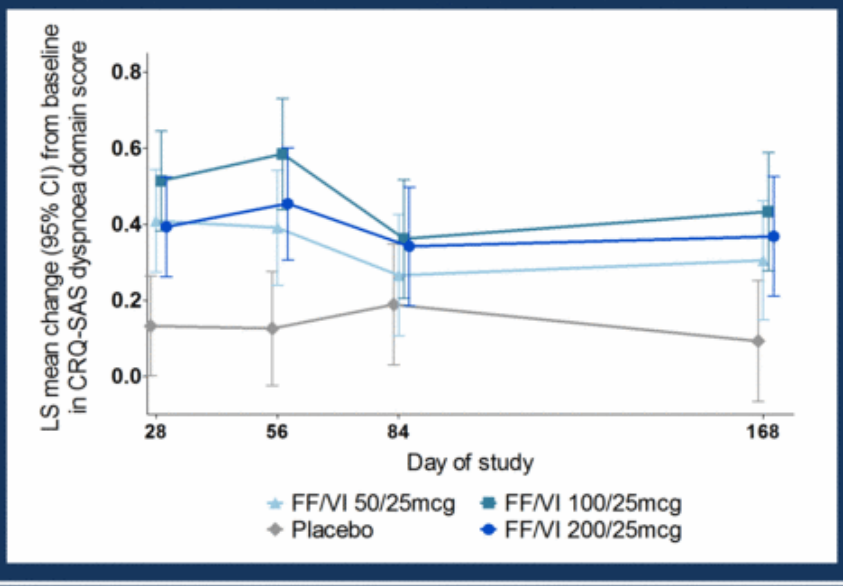
Primary endpoint: trough FEV_1 at Week 24



	FF/VI 50/25mcg	FF/VI 100/25mcg	FF/VI 200/25mcg
Day 169 LS mean change vs placebo (95% CI), L	0.140 (0.089, 0.191)	0.179 (0.129, 0.230)	0.194 (0.143, 0.245)
p-value	<0.001	<0.001	<0.001

LS=least squares; CI=confidence interval

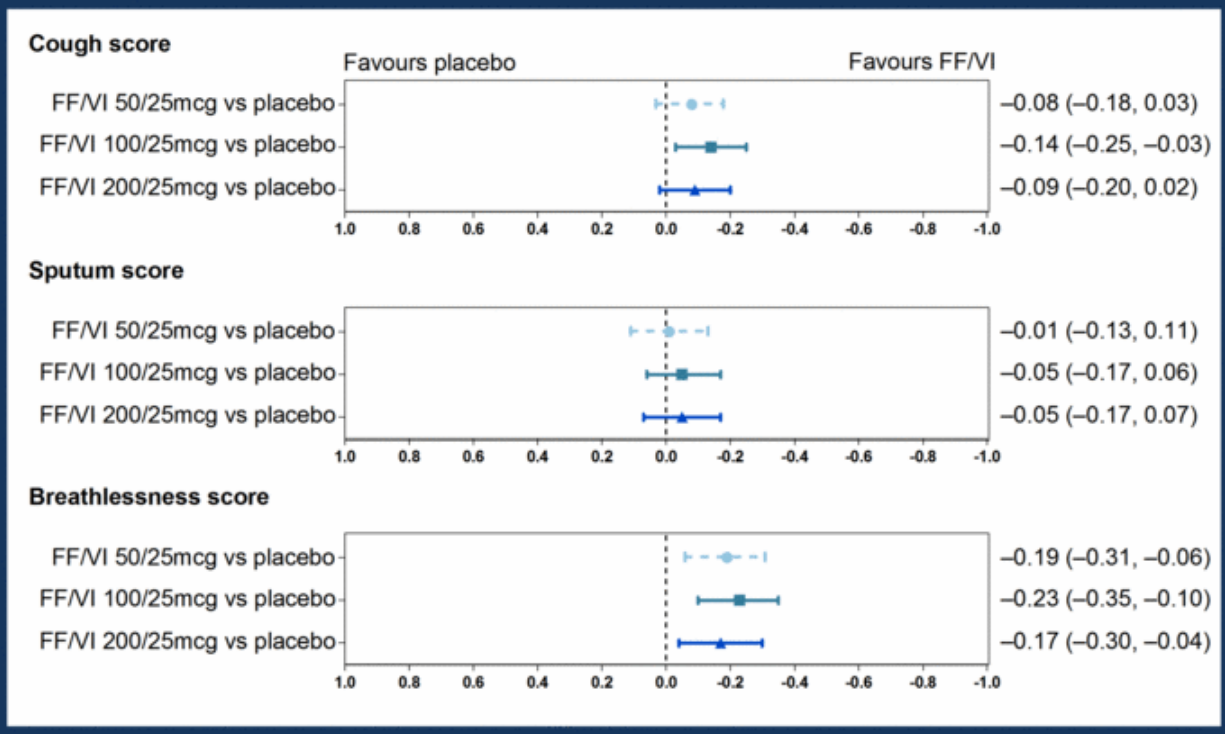
Secondary endpoint: CRQ-SAS dyspnoea domain at Week 24



	FF/VI 50/25mcg	FF/VI 100/25mcg	FF/VI 200/25mcg
Day 168 LS mean change vs placebo (95% CI)	0.21 (–0.01, 0.43)	0.34 (0.12, 0.56)	0.27 (0.05, 0.50)
p-value	0.064	0.003	0.016

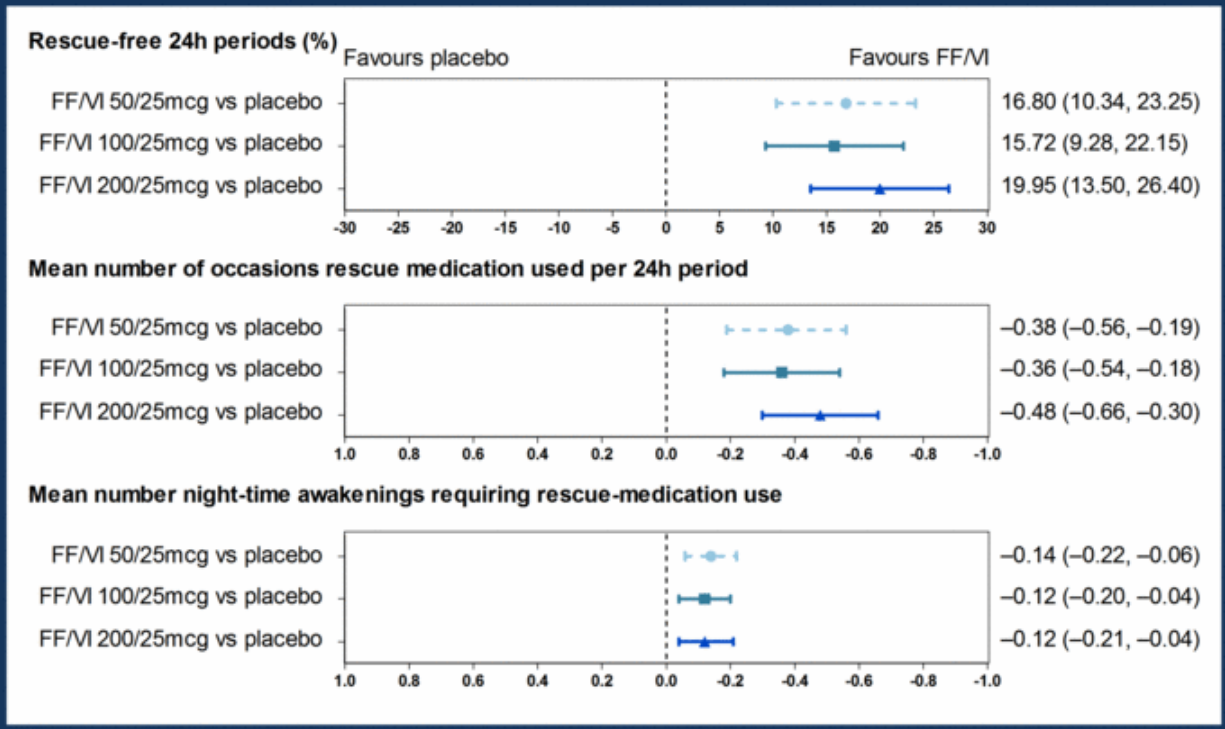
LS=least squares; CI=confidence interval

Daily diary card endpoints: COPD symptom score



Dashed error bars indicate that statistical inference cannot be made

Diary card endpoints: albuterol (rescue) use



Dashed error bars indicate that statistical inference cannot be made

COPD Assessment Test (CAT)

	Placebo (n=162)	FF/VI 50/25 (n=160)	FF/VI 100/25 (n=161)	FF/VI 200/25 (n=160)
Baseline				
n	*161*	*159*	*161*	*160*
Mean (SD)	14.0 (7.23)	15.1 (7.46)	14.2 (7.15)	14.2 (6.84)
Day 168				
n	*129*	*136*	*138*	*134*
Mean (SD)	13.5 (6.30)	13.1 (7.07)	11.6 (6.62)	12.1 (7.19)
Change from baseline				
Mean (SD)	–0.0 (7.93)	–1.8 (7.88)	–2.2 (6.65)	–1.6 (7.82)

- Decrease (improvement in health status) in mean CAT score exceeds estimated minimal clinically important differences of 1.3[1] or 1.6[2] with all three strengths of FF/VI
- Largest decrease with FF/VI 100/25mcg

[1]Dodd JW. et al. *Thorax* 2011;66:425–9; [2]Jones PW. et al. *Eur Respir J* 2009;34:648–54

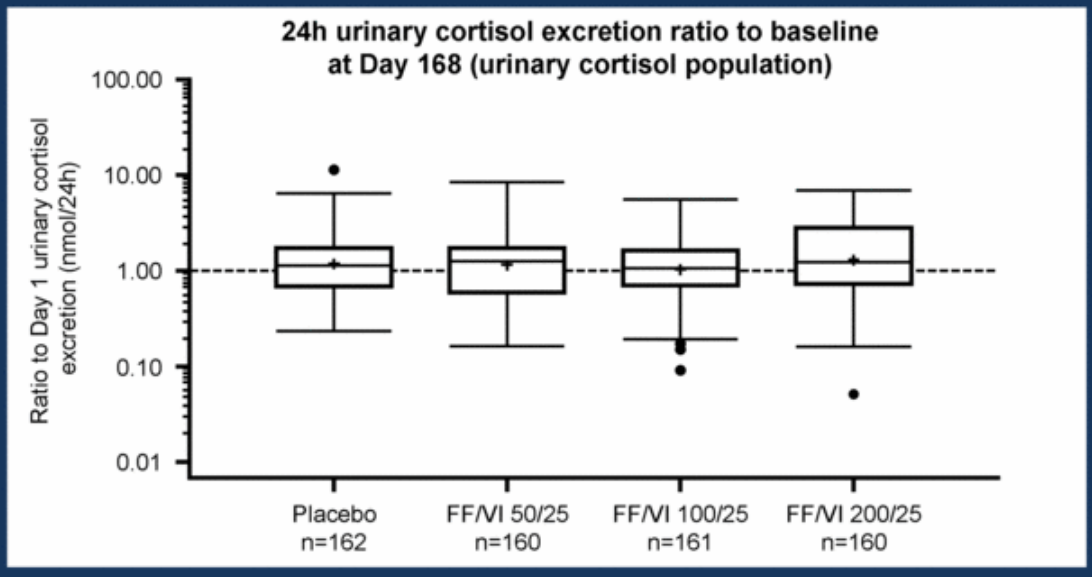
Adverse events (AEs)

	Placebo (n=162)	FF/VI 50/25 (n=160)	FF/VI 100/25 (n=161)	FF/VI 200/25 (n=160)
Any on-treatment AE	63 (39)	64 (40)	59 (37)	77 (48)
Any serious AE	14 (9)	9 (6)	7 (4)	14 (9)
Any fatal AE	2 (1)	1 (<1)	1 (<1)	1 (<1)
Most frequent on-treatment AEs[a]				
Upper respiratory tract infection	15 (9)	16 (10)	19 (12)	14 (9)
Nasopharyngitis	7 (4)	13 (8)	9 (6)	19 (12)
COPD exacerbation[b]	7 (4)	3 (2)	3 (2)	8 (5)
Pyrexia	5 (3)	3 (2)	4 (2)	3 (2)
Cough	2 (1)	2 (1)	6 (4)	3 (2)
Pneumonia	4 (2)	2 (1)	1 (<1)	5 (3)
Hypertension	1 (<1)	1 (<1)	2 (1)	5 (3)
Oropharyngeal pain	0	0	2 (1)	4 (3)

ITT population; [a]Frequency ≥3% in any group; [b]Reported as a serious AE

Safety: other

- No indication of treatment effect on glucose or potassium
- No clinically significant changes in vital signs versus placebo
- No changes of clinical concern for ECG parameters
- No indication of treatment effect on urinary cortisol excretion



Summary

- All three strengths of FF/VI improved trough FEV_1
- Improvements observed on CRQ-SAS Dyspnoea domain but not clinically important
- Improvements observed on diary card measures
  - Treatment benefit perceived by patients was also demonstrated by CAT scores
- All three strengths of FF/VI displayed acceptable safety profiles consistent with historical data[1,2]

[1]Kerwin EM. et al. *Respir Med* 2013;107:560–9; [2]Martinez FJ. et al. *Respir Med* 2013;107:550–9

Conclusions

FF/VI 100/25mcg is an appropriate therapeutic strength for the treatment of COPD in Asian patients based on the totality of data from this study.

POSTER NO. PS272

Ethnic sensitivity assessment of fluticasone furoate (FF)/vilanterol (VI) in asthma patients in Japan and Korea: a pre-specified subgroup analysis

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INTRODUCTION

- Inhaled corticosteroid (ICS)/long-acting beta$_2$-agonist (LABA) combinations are recommended by Japanese(1) and global asthma guidelines(2) for asthma patients uncontrolled on ICS alone.
- FF/VI is a once-daily ICS/LABA combination therapy delivered via the ELLIPTA™ dry powder inhaler, which is effective for 24h.
- Responses to pharmacotherapy can vary across ethnic groups(3),(4) including in Japanese patients.

OBJECTIVES

- To establish whether doses of FF/VI recommended from multinational studies are relevant to asthma patients in Japan.
- To compare the efficacy, safety, PK and PD data for FF/VI in patients from Japan and/or Korea with data from patients not from Japan or Korea
  - Patients from Korea were included due to similarities in a range of intrinsic and extrinsic ethnic factors between the populations of Japan and Korea.(5)–(7)

METHODS

- A pre-specified subgroup analysis of multicentre, randomised, double-blind, parallel-group international studies that included asthma patients from Japan and/or Korea.
- Inclusion criteria: ≥12 years of age, pre-bronchodilator % predicted forced expiratory volume in one second (FEV_1) of 40–90%, FEV_1 reversibility of ≥12% and ≥200mL.
- Efficacy results were pooled from three Phase III studies, ranging from 12 to 76 weeks duration, that included patients from Japan (GSK study numbers: HZA106827; HZA106829; HZA106837).
- Change from baseline in trough FEV_1 after 12 weeks with once-daily FF/VI 100/25mcg, once-daily FF 100mcg or placebo was analysed across two studies (HZA106827; HZA106837) and data for once-daily FF/VI 200/25mcg, once-daily FF 200mcg and twice-daily fluticasone propionate (FP) 500mcg were from one study (HZA106829).
- Safety data were pooled from the three studies noted above and an additional three placebo-controlled Phase IIb studies, ranging from 28 days to 8 weeks duration, that included patients from Korea (B2C109575; FFA109685; FFA109687).
- PK data were estimated based on a *post-hoc* analysis of population PK data for FF(8) and of study DB111207 data for VI(9); PD data, including 24h urinary cortisol excretion, were assessed.

RESULTS

Table 1. Demographic and baseline characteristics

Demographic and baseline characteristics (Efficacy population)

	Japan N=148	Not-Japan N=3066	Overall N=3214
Age(1) (years)	47.5 (14.66)	41.9 (16.63)	42.2 (16.59)
Male (%)	38	36	36
Weight(1) (kg)	62.5 (13.63)	76.2 (19.29)	75.5 (19.28)
Height(1) (cm)	160.7 (8.05)	165.7 (9.98)	165.5 (9.96)
FEV_1(1) (L)	1.933(2) (0.5481)	2.231(3) (0.6469)	2.218(4) (0.6456)
% Predicted FEV_1(1)	74.7(2) (11.13)	70.6(3) (11.18)	70.8(4) (11.21)

Demographic characteristics (Safety population)

	Japan+Korea N=194	Not-Japan+Korea N=4037	Overall N=4231
Age(1) (years)	46.1 (15.00)	41.3 (16.47)	41.5 (16.44)
Male (%)	40	37	37
Weight(1) (kg)	63.5 (13.37)	76.1(5) (19.68)	75.5(6) (19.61)
Height(1) (cm)	161.6 (8.46)	165.7 (10.21)	165.5 (10.17)

(1)Mean (SD); (2)n=147; (3)n=3059; (4)n=3206; (5)n=4036; (6)n=4230

Efficacy

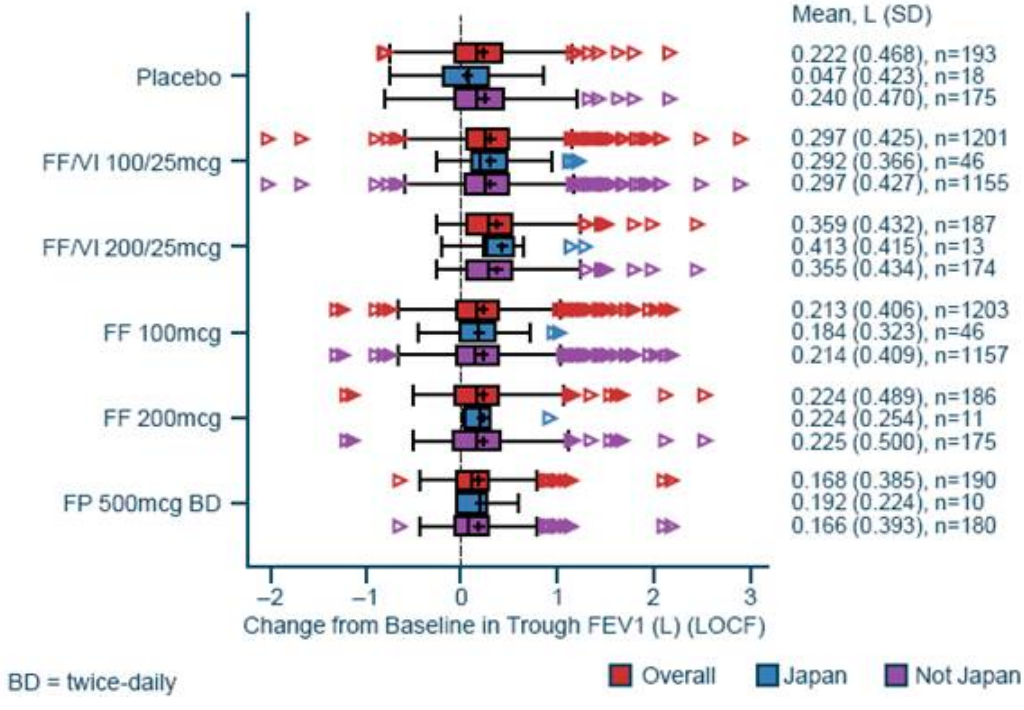
- Efficacy data were compared between patients (N=3214) from Japan and 'Not-Japan'; 85% (N=2739) completed the studies.
- Improvements in trough FEV_1 were reported in all populations for FF/VI 100/25mcg and FF 100mcg versus placebo and for FF/VI 100/25mcg versus FF 100mcg (**Table 2**)
  - There was no evidence of a statistically significant difference in treatment effect between patients from Japan and Not-Japan (p=0.403).
- Changes from baseline in FEV_1 were similar with FF/VI 200/25mcg and FF 200mcg in patients from Japan and the overall population (**Figure 1**)
  - Improvements were greater than with twice-daily FP 500mcg.

Table 2. Comparison of change from baseline in trough FEV_1 at Week 12 between treatment arms (Efficacy population)

		FF/VI 100/25mcg	FF 100mcg
Overall	N	1201	1203
	Difference vs. placebo(1)	0.181 (0.111, 0.252) **p<0.001**	0.105 (0.034, 0.175) **p=0.003**
	Difference vs. FF 100mcg	0. 077 (0.045, 0.108) **p<0.001**	—
Japan	n	46	46
	Difference vs. placebo(2)	0.323 (0.104, 0.542)	0.216 (–0.003, 0.436)
	Difference vs. FF 100mcg	0.107 (–0.056, 0.270)	—
Not-Japan	n	1155	1157
	Difference vs. placebo(3)	0.168 (0.095, 0.241)	0.093 (0.020, 0.166)
	Difference vs. FF 100mcg	0.075 (0.043, 0.108)	—

Least squares mean change (95% confidence interval). Studies included: HZA106827, HZA106837. Data were analysed using a Last Observation Carried Forward Analysis of Covariance model, with terms for baseline FEV_1, region, gender, age, treatment group, study & region by treatment interaction. [1]n=193; [2]n=18, [3]n=175

Figure 1. Box plot of change from baseline in trough FEV_1 at Week 12 by geographic region (Efficacy population)



Safety

- Safety data were compared between patients (N=4231) from Japan/Korea and Not-Japan/Korea; N=3584 (85%) completed the studies.
- In all active treatment groups, a greater proportion of patients from Japan/Korea versus Not-Japan/Korea reported on-treatment adverse events; this trend was also observed in the placebo group, suggesting that this is not related to FF or VI (**Table 3**).

Table 3. Summary of on-treatment adverse events and serious adverse events (Safety population)

	Placebo	FF/VI 100/25mcg	FF/VI 200/25 mcg	FF 100mcg	FF 200mcg
All on-treatment adverse events					
Japan+Korea	12/29 (41)	37/47 (79)(1)	9/14 (64)(1)	38/55 (69)	16/22 (73)
Not-Japan/Korea	87/375 (23)	658/1163 (57)	83/183 (45)	744/1375 (54)	134/386 (36)
Overall	99/404 (25)	695/1210 (57)	92/197 (47)	782/1430 (55)	150/390 (38)
On-treatment non-fatal serious adverse events					
Japan+Korea	0/29 (0)	1/47 (2)(1)	0/14 (0)(1)	1/55 (2)	0/22 (0)
Overall	0/404 (0)	40/1210 (3)	6/197 (3)	30/1430 (2)	1/390 (<1)
On-treatment fatal adverse events					
Japan+Korea	0/29 (0)	0/47 (0)(1)	0/14 (0)(1)	0/55 (0)	0/22 (0)
Overall	0/404 (0)	1/1210(2) (<1)	0/197 (0)	1/1430 (<1)	0/390 (0)

Data presented as number of patients with an adverse event/number of patients in population group (%);

(1)Only subjects from Japan;
(2)One additional subject (South East Asian) died during follow-up

Safety (cont'd)

- Serious adverse events reported for patients from Japan+Korea (1 FF/VI 100/25mcg, 1 FF 100mcg: both subarachnoid haemorrhage) were not considered drug related.

PK/PD

- Estimated FF $AUC_{(0-24)}$ and VI C_{max} were higher in Japanese versus White/Caucasian patients (**Table 4**).

PK/PD (cont'd)

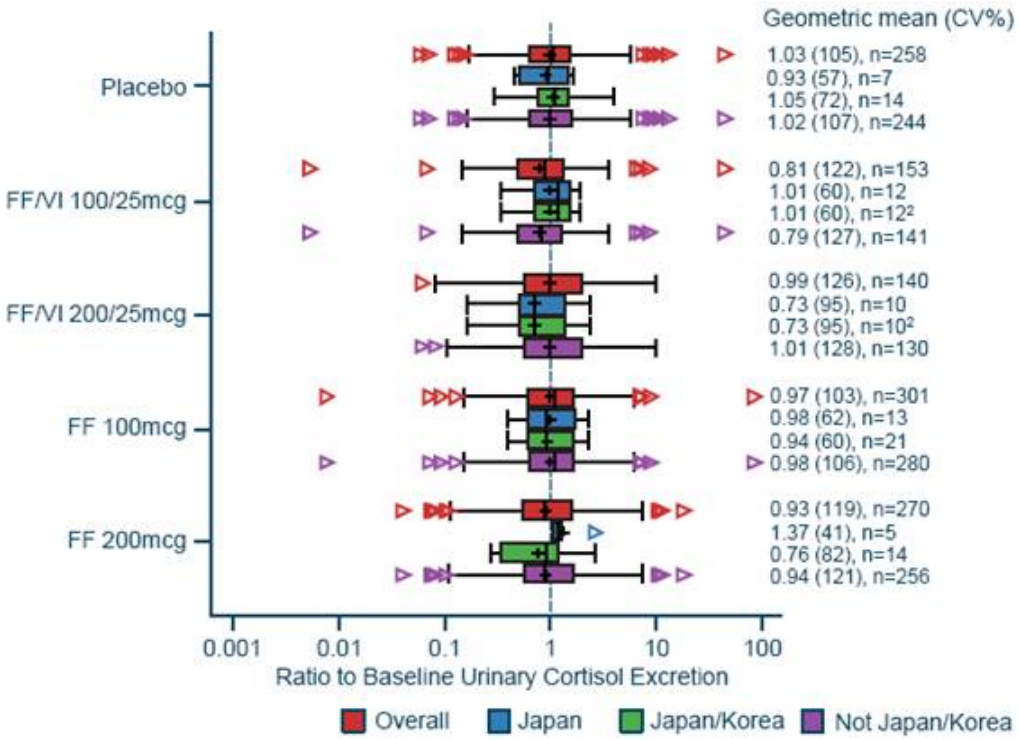
- No clinically relevant effects on cortisol concentrations (**Figure 2**) or heart rate were observed.
- The PK profile of FF at clinical doses (≤200mcg) did not differ when administered simultaneously with VI 25mcg compared with FF alone for either Japanese or White/Caucasian patients.

Table 4. Model predicted PK parameters

Race	Treatment	N	C max (pg/mL)	AUC (0-24) (pg.h/mL)
Model predicted FF PK parameters				
Japanese	FF/VI 100/25mcg	14	18.0 [11.8, 26.1]	348.6 [214.7, 510.8]
	FF 100mcg	15	19.9 [13.2, 27.8]	304.6 [240.4, 382.6]
	FF/VI 200/25mcg	13	42.4 [28.2, 59.7]	605.1 [489.2, 871.8]
	FF 200mcg	8	34.6 [24.2, 49.8]	581.9 [374.1, 855.1]
White / Caucasian	FF/VI 100/25mcg; FF 100mcg	492	15.2 [14.9, 15.6]	232.2 [226.0, 238.5]
	FF/VI 200/25mcg; FF 200mcg	471	30.0 [29.1, 30.8]	471.6 [459.0, 484.1]
Model predicted VI PK parameters				
Japanese	FF/VI 100/25mcg	14	113.3 [38.7, 243.7]	139.1 [117.2, 159.0]
	FF/VI 200/25mcg	13	144.9 [63.4, 236.1]	146.1 [119.4, 168.0]
White / Caucasian	FF/VI 100/25mcg; FF/VI 200/25mcg	660	42.2 [39.7, 44.9]	165.7 [160.2, 171.4]

Geometric mean (95% confidence interval); FF data from *post-hoc* analysis of population PK data(8); VI data from post-hoc analysis of study DB111207(9)

Figure 2. Ratio of 24h urinary cortisol excretion to baseline at the end of treatment (Urinary cortisol population(1))



(1)Urinary cortisol population: subset of patients from Safety population, that were not considered to have confounding factors, and for whom urine samples were available;
(2)Only subjects from Japan

CONCLUSIONS

- The efficacy and safety profile of FF/VI is similar in asthma patients from Japan+Korea and Not-Japan+Korea.
- The FF/VI clinical doses recommended based on global studies are also suitable for asthma patients in Japan.

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(9) Nakahara N, et al. *Int J Clin Pharmacol Ther* 2013;51:660–72

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