

**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): **October 26, 2014**

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)

**951 Gateway Boulevard
South San Francisco, California 94080
(650) 238-9600**

(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.

On October 26, 2014 at CHEST 2014 in Austin, Texas, GlaxoSmithKline plc (GSK) presented data from two Phase 3 studies comparing the efficacy and safety of ANORO[®] (umeclidinium/vilanterol "UMEC/VI") once daily versus ADVAIR[®] (fluticasone/salmeterol combination "FSC") twice daily in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD) and infrequent COPD exacerbations. ANORO[®] is a once-daily combination treatment comprising two bronchodilators, UMEC, a long-acting muscarinic antagonist (LAMA), and VI, a long-acting beta₂ agonist (LABA), in a single inhaler, the ELLIPTA[®]. UMEC/VI has been developed under the 2002 LABA collaboration between Glaxo Group Limited and Theravance, Inc. The slide presentation is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Efficacy and Safety of Umeclidinium/Vilanterol (UMEC/VI) Once Daily (OD) vs Fluticasone/Salmeterol Combination (FSC) Twice Daily (BD) in Patients With Moderate-to-Severe COPD and Infrequent COPD Exacerbations

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: October 27, 2014

By: /s/ Michael W. Aguiar
Michael W. Aguiar
Chief Executive Officer

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EXHIBIT INDEX

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Presentation No: 73A

Efficacy and safety of umeclidinium/vilanterol (UMEC/VI) once daily (OD) vs fluticasone/salmeterol (FSC) combination twice daily (BD) in patients with moderate-to-severe COPD and infrequent COPD exacerbations

James F. Donohue, MD, FCCP

Department of Medicine, University of North Carolina, North Carolina, USA



Disclosures

- Jim Donohue has the following statement of interest:
 - served as consultant to Almirall, AstraZeneca, Boehringer Ingelheim, Elevation Pharmaceuticals, Forest Laboratories, GSK, Mylan, Novartis, Pearl Pharmaceuticals, Pfizer and Sunovion
 - served as a member of Drug Safety Monitoring Boards for the NIH, Novartis, Otsuka, Pearl and Teva



Off-label discussion declaration

- I will not be discussing off-label uses of the treatments presented here



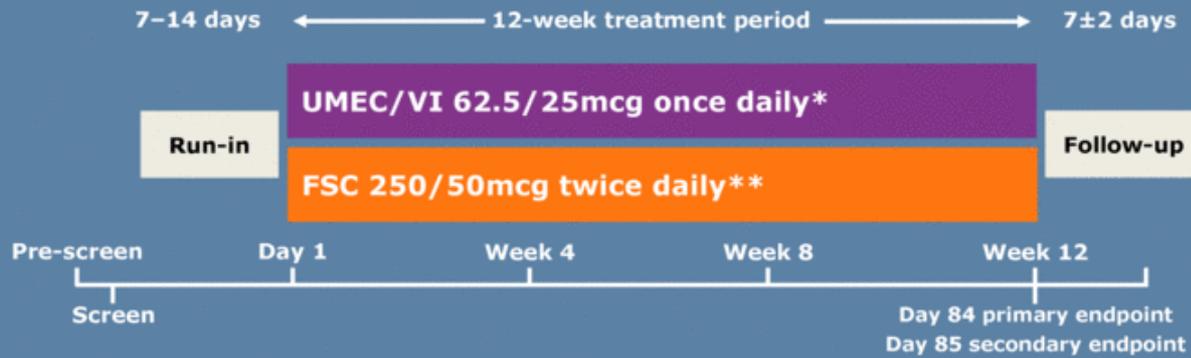
Primary objective

- To compare the efficacy and safety of once-daily UMEC/VI 62.5/25mcg with twice-daily FSC 250/50mcg over 12 weeks in patients with moderate-to-severe COPD with a history of infrequent COPD exacerbations
- Two studies were conducted
 - DB2114930 (NCT01817764)
 - DB2114951 (NCT01879410)

COPD: chronic obstructive pulmonary disease; FSC: fluticasone propionate/salmeterol; UMEC: umeclidinium; VI: vilanterol



Study design



* delivered doses 55/22mcg via ELLIPTA® dry powder inhaler
** via DISKUS® inhaler



Key inclusion and exclusion criteria

- Inclusion
 - males or females ≥ 40 years old with moderate-to-severe COPD
 - post-salbutamol $FEV_1 \geq 30\%$ and $\leq 70\%$ predicted normal
 - dyspnea score ≥ 2 (mMRC Dyspnea Scale)
- Exclusion
 - documented history of ≥ 1 COPD exacerbation requiring oral corticosteroids, antibiotics and/or hospitalization in the year prior to screening

FEV_1 : forced expiratory volume in 1s; mMRC: modified Medical Research Council



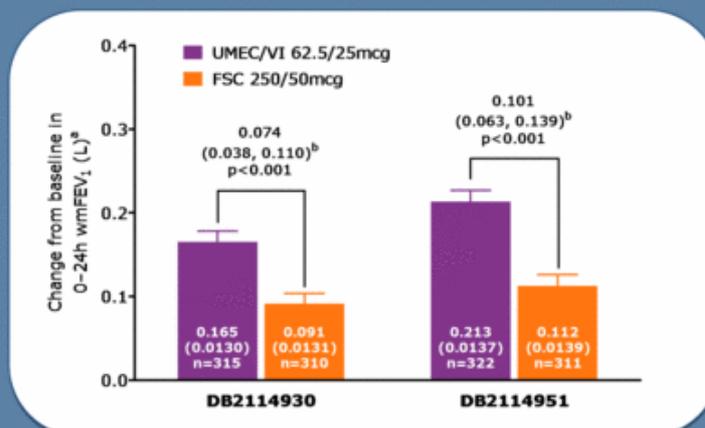
Key baseline demographics and disease characteristics (ITT)

	DB2114930 (N=706) ^a	DB2114951 (N=697) ^b
Age, years ^c	62.8 (8.97)	63.6 (8.55)
Males, n (%)	497 (70)	528 (76)
Current smoker, n (%)	304 (43)	363 (52)
Pre-salbutamol FEV ₁ , L ^c	1.322 (0.4312)	1.335 (0.4530) ^d
Post-salbutamol FEV ₁ , L ^c	1.451 (0.4440) ^e	1.488 (0.4603)
GOLD stage (% predicted FEV ₁) ^f		
Stage II	347 (49)	346 (50)
Stage III	357 (51)	351 (50)
Reversible to salbutamol, n (%)	189 (27) ^e	239 (34) ^d
mMRC dyspnea scale score ^g	2.0 (2-4)	2.0 (2-4)

^an=353 for UMEC/VI and FSC groups; ^bn=349 (UMEC/VI) and 348 (FSC); ^cmean (standard deviation); ^dn=696; ^en=704; ^fn=704 in DB2114930; ^gmedian (range)
ITT: intent-to-treat



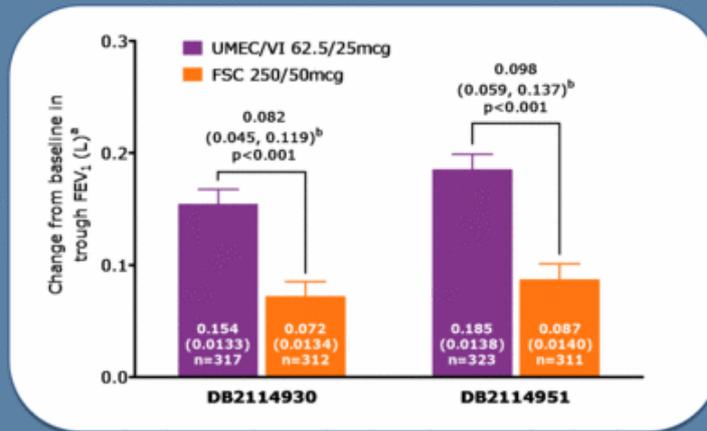
UMEC/VI demonstrated greater improvements in 0-24h wmFEV₁ than FSC on day 84 (primary endpoint)



^aLS mean change (SE) from baseline on day 84; ^btreatment difference (95% confidence interval)
LS: least-squares; SE: standard error; wm: weighted mean



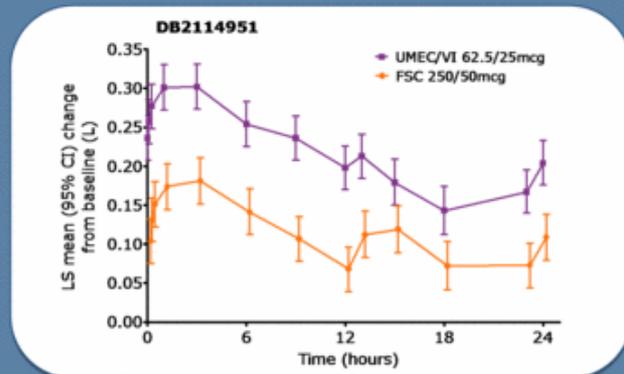
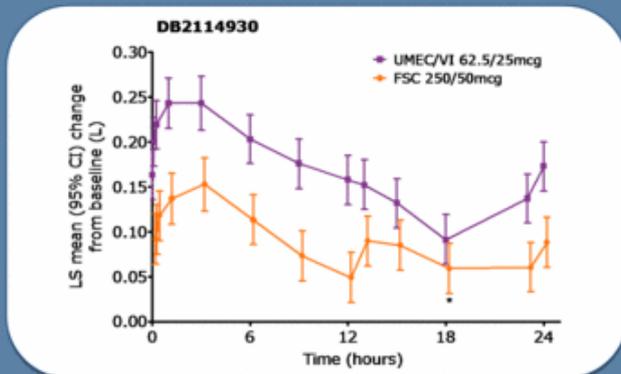
UMEC/VI demonstrated greater improvements in trough FEV₁ than FSC on day 85 (secondary endpoint)



^aLS mean change (SE) from baseline on day 85; ^btreatment difference (95% confidence interval)



UMEC/VI demonstrated greater improvements in serial FEV₁ than FSC on day 84

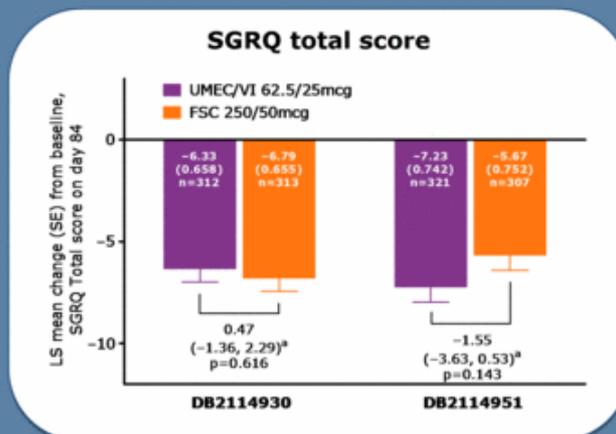
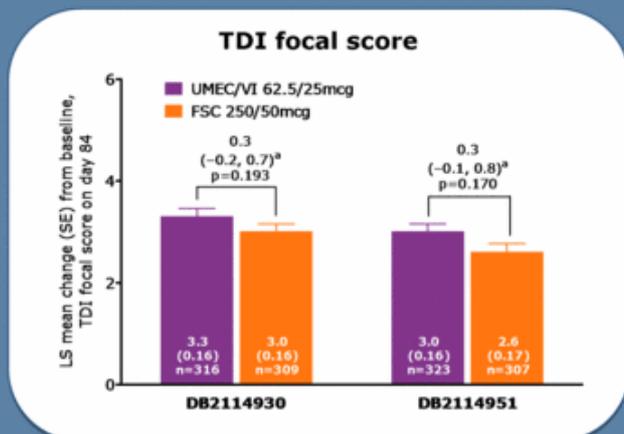


- Statistically significant improvements with UMEC/VI versus FSC were seen at each time point on day 84 in both studies except at 18h* in DB2114930 (p=0.107)

CI: confidence interval



Similar improvements were observed in TDI and SGRQ with UMEC/VI and FSC



*treatment difference (95% confidence interval)



Similar safety profiles were observed with UMEC/VI and FSC

Incidence, n (%)	DB2114930		DB2114951	
	UMEC/VI 62.5/25mcg (N=353)	FSC 250/50mcg (N=353)	UMEC/VI 62.5/25mcg (N=349)	FSC 250/50mcg (N=348)
Total AEs	93 (26)	96 (27)	104 (30)	108 (31)
Serious AEs				
Any	6 (2)	10 (3)	11 (3)	13 (4)
Fatal	0	1 (<1)	2 (<1)	3 (<1)
AEs of special interest				
Cardiovascular	4 (1)	7 (2)	10 (3)	7 (2)
Pneumonia	1 (<1)	4 (1)	2 (<1)	4 (1)
LRTI (excl. pneumonia)	0	3 (<1)	3 (<1)	2 (<1)
COPD exacerbations	12 (3)	11 (3)	9 (3)	11 (3)

AE: adverse event; excl: excluding; LRTI: lower respiratory tract infection



Conclusions

- Once-daily UMEC/VI significantly improved lung function vs twice-daily FSC 250/50mcg in moderate-to-severe COPD patients with infrequent COPD exacerbations
- Both treatments improved dyspnea and QoL
- Overall, the AE incidence was similar between treatment groups
- These findings suggest that treatment with UMEC/VI provides greater lung function benefits than FSC in moderate-to-severe COPD patients with infrequent COPD exacerbations



Acknowledgments

- Patients, investigators and staff at the 63 study centers in Argentina, Chile, Greece, Peru, Romania, Ukraine and the USA (DB2114930) and at the 71 study centers in Chile, Mexico, Norway, Romania, Ukraine, Russian Federation, South Africa and the USA (DB2114951)
- Funded by GSK (DB2114930 / NCT01817764; DB2114951 / NCT01879410)

