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 10, 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 September 10, 2013 at the European Respiratory Society (ERS) Annual Congress 2013 in Barcelona, Spain, GlaxoSmithKline (GSK) presented posters containing information from Phase 3 studies of umeclidinium/vilanterol (UMEC/VI) in chronic obstructive pulmonary disease (COPD). UMEC/VI is a combination of two investigational bronchodilator molecules - GSK573719 or umeclidinium, a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta$_2$ agonist (LABA), administered using the ELLIPTA™ inhaler. UMEC/VI is under regulatory review by the U.S. Food and Drug Administration (FDA), European Medicines Agency and the Japanese Ministry of Health, Labor and Welfare. Marketing applications for UMEC/VI have been submitted to regulatory authorities in a number of other countries worldwide. UMEC/VI is in development under the LABA collaboration agreement between Glaxo Group Limited and Theravance, Inc. The posters are filed as Exhibits 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	Efficacy and safety of umeclidinium/vilanterol compared with umeclidinium or tiotropium in COPD
Exhibit 99.2	Use of a new dry powder inhaler to deliver umeclidinium/vilanterol in the treatment of 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: September 10, 2013

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Efficacy and safety of umeclidinium/vilanterol compared with umeclidinium or tiotropium in COPD
99.2	Use of a new dry powder inhaler to deliver umeclidinium/vilanterol in the treatment of COPD

Poster No. P3640

Efficacy and safety of umeclidinium/vilanterol compared with umeclidinium or tiotropium in COPD

Marc Decramer,(1) Antonio Anzueto,(2) Edward Kerwin,(3) Nathalie Richard,(4) Glenn Crater,(4) Maggie Tabberer,(5) Stephanie Harris,(4) Alison Church(4)

(1)University Hospital, Leuven, Belgium; (2)University of Texas Health, Houston, Texas, USA; (3)Clinical Research Institute of Southern Oregon, PC, Oregon, USA; (4)GlaxoSmithKline, Respiratory, Research Triangle Park, North Carolina, USA; (5)GlaxoSmithKline, Stockley Park, Uxbridge, UK

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 combined long-acting muscarinic antagonist/long-acting β_2-agonist bronchodilator in development for the maintenance treatment of COPD.

AIMS

- To evaluate the efficacy and safety of two once-daily doses of UMEC/VI (125/25 mcg [delivering 113/22 mcg] and 62.5/25 mcg [delivering 55/22 mcg]) compared with UMEC 125 mcg (delivering 113 mcg) or tiotropium (TIO) 18 mcg monotherapies in patients with COPD.

METHODS

Study design and treatments

- This was a 24-week, multicentre, randomised, blinded, double-dummy, parallel-group study (DB2113374; NCT01316913).
- Key eligibility criteria: age $\geq$40 years; clinically established history of COPD; current or former cigarette smokers with a smoking history of $\geq$10 pack-years; post-salbutamol forced expiratory volume in one second (FEV_1)/forced vital capacity (FVC) ratio <0.7; post-salbutamol FEV_1 $\leq$70% of predicted normal values; and a modified Medical Research Council Dyspnoea Scale(3) score $\geq$2. Concurrent use of inhaled corticosteroids (ICS) and rescue use of salbutamol was allowed.
- Following a 7-10-day run-in period, patients were randomised 1:1:1:1 to 24 weeks of treatment with UMEC/VI 125/25, UMEC/VI 62.5/25, UMEC 125 or TIO 18.
- UMEC/VI, UMEC and matching placebo were administered via ELLIPTA™* dry powder inhaler (DPI); TIO and corresponding placebo capsules were administered via HandiHaler® DPI. Each patient took one dose from the HandiHaler® DPI and one dose from the ELLIPTA™ DPI each morning. TIO capsules had trade markings but placebo did not. With a parallel group design, the capsule type was consistent for each patient for the duration of the study. Blister packages were covered with opaque over-labels to shield information appearing on the blister packaging of TIO. Dosing in the clinic was administered without the presence of staff involved with safety and efficacy assessments.
- All patients provided written, informed consent before study participation. The study was conducted in accordance with the declaration of Helsinki and Good Clinical Practice guidelines. Institutional Review Board approval was obtained.

Endpoints

- *Primary efficacy:* trough FEV_1 at Day 169, defined as the mean of FEV_1 values obtained 23 and 24 h after dosing on Day 168.
- *Secondary efficacy:* weighted mean (WM) FEV_1 over 0-6 h post-dose at Day 168.
- *Additional efficacy:* mean transition dyspnoea index (TDI) focal score; St George's Respiratory Questionnaire (SGRQ) score; rescue salbutamol use and time to first COPD exacerbation.
- *Safety:* adverse events (AEs); vital signs; 12-lead electrocardiography (ECG); and clinical chemistry/haematology measurements.

RESULTS

Patient demographics and baseline characteristics

- A total of 1191 patients were enrolled; 869 were included in the intention-to-treat (ITT) population (i.e., randomised and received at least one dose of study medication).
- Patient demographics and baseline characteristics were similar across treatment groups (Table 1).

**ELLIPTA™ is a trademark of the GlaxoSmithKline group of companies*

TABLE 1. PATIENT DEMOGRAPHICS AND BASELINE CHARACTERISTICS (ITT POPULATION)

	UMEC 125 (N=222)	UMEC/VI 62.5/25 (N=217)	UMEC/VI 125/25 (N=215)	TIO 18 (N=215)
Age, years	64.5 (8.33)	65.0 (8.62)	63.8 (8.51)	65.2 (8.30)
Male, n (%)	148 (67)	140 (65)	148 (69)	153 (71)
Current smoker, n (%)(a)	98 (44)	92 (42)	96 (45)	102 (47)
Smoking pack-years	47.6 (27.58)	47.8 (26.13)	46.9 (24.90)	54.0 (31.59)
Cardiovascular risk factor, n (%)(b)	127 (57)	131 (60)	121 (56)	123 (57)
ICS use, n (%)(c)	124 (56)	103 (47)	113 (53)	115 (53)
Pre-bronchodilator FEV_1, L	1.140 (0.4479)	1.170 (0.4655)	1.159 (0.4384)	1.175 (0.4287)
Post-salbutamol FEV_1, L	1.294 (0.4679)	1.322 (0.4899)	1.313 (0.4235)	1.328 (0.4310)
Reversibility to salbutamol, %	16.1 (15.25)	14.9 (14.95)	15.8 (15.17)	15.5 (15.55)
Post-salbutamol % predicted FEV_1	46.2 (13.03)	47.7 (13.55)	47.1 (12.88)	47.4 (13.10)
Post-salbutamol FEV_1/FVC	45.29 (11.37)	46.23 (11.86)	45.94 (10.39)	45.80 (11.65)

Values are presented as mean (standard deviation) unless otherwise stated.

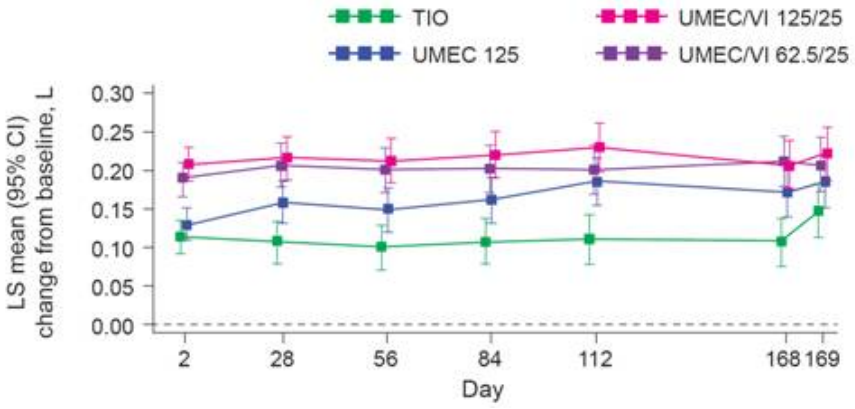
(a)Patient was reclassified as a current smoker if he/she smoked within 6 months of screening; (b)Current medical history of angina pectoris, diabetes, hyperlipidaemia, hypertension or myocardial infarction; (c)ICS use was defined as those patients who were currently taking ICS medications at the screening visit.

Primary efficacy: trough FEV_1

- Treatment with UMEC/VI 125/25 resulted in a statistically significant improvement in trough FEV_1 at Day 169 compared with TIO (p=0.003) but not UMEC 125 (p=0.142) (Figure 1, Table 2).

- An improvement was also observed with UMEC/VI 62.5/25 *vs* TIO (p=0.018) but not *vs* UMEC 125 (p=0.377).

FIGURE 1. TROUGH FEV_1 (ITT POPULATION)



CI, confidence interval; LS, least squares.

Secondary efficacy: 0-6 h post-dose WM FEV_1

- Both UMEC/VI doses showed improvements in 0-6 h post-dose WM FEV_1 at Day 168 compared with TIO and UMEC 125 (Figure 2, Table 2).

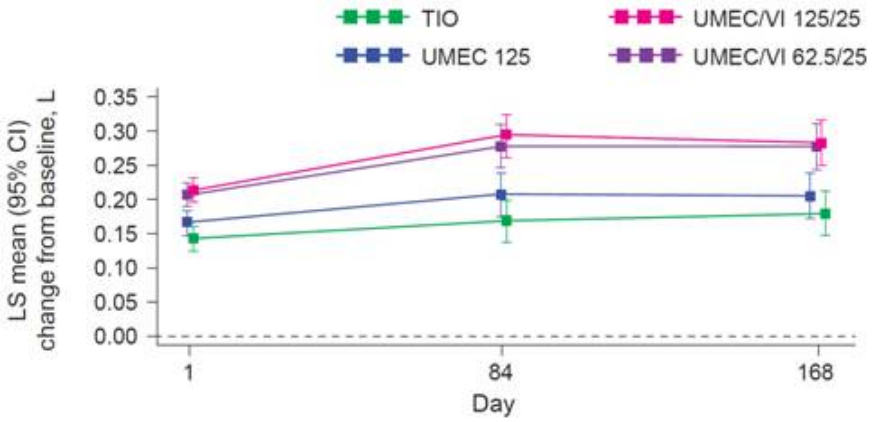
TABLE 2. EFFICACY OUTCOMES (ITT POPULATION)

	UMEC 125 (N=222)	TIO 18 (N=215)
Trough FEV_1 at Day 169, L		
Difference *vs* monotherapy (95% CI)		
UMEC/VI 125/25	0.037 (–0.012, 0.087)	0.074** (0.025, 0.123)
UMEC/VI 62.5/25	0.022 (–0.027, 0.072)	0.060* (0.010, 0.109)
0—6 h WM FEV_1 at Day 168, L		
Difference *vs* monotherapy (95% CI)		
UMEC/VI 125/25	0.076*** (0.029, 0.122)	0.101*** (0.055, 0.147)
UMEC/VI 62.5/25	0.070** (0.024, 0.117)	0.096*** (0.050, 0.142)
TDI responder at Day 168(a)		
Odds ratio *vs* monotherapy (95% CI)		
UMEC/VI 125/25	1.2 (0.8, 1.8)	1.2 (0.8, 1.8)
UMEC/VI 62.5/25	1.3 (0.9, 2.0)	1.3 (0.9, 1.9)
SGRQ responder at Day 168(b)		
Odds ratio *vs* monotherapy (95% CI)		
UMEC/VI 125/25	1.1 (0.8, 1.7)	0.9 (0.6, 1.3)
UMEC/VI 62.5/25	1.3 (0.9, 1.9)	1.0 (0.6, 1.5)

Salbutamol use, Weeks 1—24, puffs/day		
Difference *vs* monotherapy (95% CI)		
UMEC/VI 125/25	-1.1*** (-1.7, -0.5)	-1.1*** (-1.7, -0.5)
UMEC/VI 62.5/25	–0.6 (–1.2, 0.0)	–0.6 (–1.2, 0.0)

***p≤0.001; **p≤0.01; *p≤0.05 for combinations *vs* monotherapy; values in brackets = 95% CIs.
(a)Response defined as an improvement of at least 1 unit in TDI focal score; (b)Response defined as an improvement of at least 4 units in SGRQ score.

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



Efficacy: additional endpoints

- UMEC/VI 125/25 reduced salbutamol use in comparison with both TIO and UMEC 125 monotherapies (Table 2).
- On-treatment COPD exacerbations were observed in 12% of patients receiving UMEC/VI 62.5/25 or UMEC 125 and 7% of patients receiving UMEC/VI 125/25 or TIO.

Safety

- The incidence of AEs was similar across treatment groups; headache and nasopharyngitis were the most common AEs reported (Table 3).
- The incidence of on-treatment serious AEs (SAEs) ranged from 4% (TIO group) to 10% (UMEC/VI 62.5/25 group). The most common SAE was COPD.
- Four patients died during the study (one in the UMEC/VI 125/25 group, one in the UMEC/VI 62.5/25 group and two in the TIO group); none were judged to be related to study drug.

- No clinically meaningful changes in vital signs, ECG or clinical laboratory parameters were observed for UMEC/VI treatments compared with UMEC 125 or TIO monotherapies.

TABLE 3. OVERVIEW OF AEs and SAEs (ITT POPULATION)

	UMEC 125 (N=222)	UMEC/VI 62.5/25 (N=217)	UMEC/VI 125/25 (N=215)	TIO 18 (N=215)
Any on-treatment AEs, n (%)	131 (59)	127 (59)	133 (62)	126 (59)
AEs reported by ≥3% patients, n (%)				
Headache	25 (11)	21 (10)	20 (9)	15 (7)
Nasopharyngitis	6 (3)	14 (6)	16 (7)	17 (8)
Upper respiratory tract infection	17 (8)	6 (3)	10 (5)	14 (7)
Back pain	10 (5)	8 (4)	6 (3)	11 (5)
Cough	14 (6)	5 (2)	8 (4)	6 (3)
Hypertension	9 (4)	1 (<1)	4 (2)	7 (3)
Oropharyngeal pain	8 (4)	3 (1)	6 (3)	3 (1)
Diarrhoea	8 (4)	4 (2)	1 (<1)	5 (2)
Gastritis	6 (3)	6 (3)	5 (2)	1 (<1)
Pain in extremity	1 (<1)	7 (3)	6 (3)	4 (2)
Urinary tract infection	6 (3)	2 (<1)	5 (2)	4 (2)
COPD	2 (<1)	7 (3)	6 (3)	1 (<1)
Influenza	6 (3)	3 (1)	2 (<1)	5 (2)
Lower respiratory tract infection	1 (<1)	9 (4)	3 (1)	2 (<1)
Dyspnoea	6 (3)	1 (<1)	0	3 (1)
Any on-treatment SAEs, n (%)	15 (7)	22 (10)	15 (7)	9 (4)
SAEs reported by ≥1% patients, n (%)				
COPD(a)	2 (<1)	7 (3)	6 (3)	1 (<1)
Pneumonia	2 (<1)	2 (<1)	3 (1)	2 (<1)

(a) Only serious COPD was recorded as an AE

CONCLUSIONS

- Both doses of UMEC/VI improved lung function compared with TIO.
- All treatments were well tolerated and no notable treatment-related changes were observed in vital signs, ECGs or clinical laboratory parameters.
- This study supports the use of once-daily UMEC/VI as long-term maintenance treatment for COPD.

REFERENCES

(1) GOLD 2013. Available at: *http://www.Goldcopd.org/*. [Accessed August 2013].
(2) Celli BR, Macnee W. *Eur Respir J* 2004;23:932—946.
(3) Manali ED, *et al*. *BMC Pulm Med* 2010;10:32.

ACKNOWLEDGEMENTS

- M Decramer has been part of advisory boards for Altana, Boehringer Ingelheim, GlaxoSmithKline, Novartis, Pfizer, Takeda/Nycomed and Ventura. He has performed consulting work for AstraZeneca, Boehringer Ingelheim, Pfizer, Dompé, GlaxoSmithKline, Novartis and Takeda/Nycomed. He has also received lecture fees from these companies and a research grant from AstraZeneca, Boehringer Ingelheim and GlaxoSmithKline. AA has received consultancy and advisory board fees from AstraZeneca, Boehringer Ingelheim, Forest and GlaxoSmithKline. EK has served on advisory boards and speaker panels for, and/or received travel reimbursement from AstraZeneca, Forest, Ironwood, Merck, Mylan, Novartis, Pearl, Pfizer, Sanofi Aventis, Sunovion, and Targacept. He has conducted multicentre clinical research trials for approximately seventy pharmaceutical companies. AC, GC, MT, NR and SH are employees of GlaxoSmithKline and hold stocks/shares in GlaxoSmithKline.
- This study was sponsored by GlaxoSmithKline (ClinicalTrials.gov: NCT01316913, protocol number DB2113374). Editorial support (in the form of writing assistance, assembling tables and figures, collating author comments, grammatical editing and referencing) was provided by Stuart Wakelin, PhD, of FWG Scientific Communications, which was funded by GlaxoSmithKline.

Placeholder
for QR code

Presented at the European Respiratory Society (ERS) Annual Congress, Barcelona, Spain, 7–11 September, 2013

Poster No. P4145

Use of a new dry powder inhaler to deliver umeclidinium/vilanterol in the treatment of COPD

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INTRODUCTION

The dry powder inhaler (DPI) ELLIPTA™* enables simultaneous delivery of two compounds without need for co-formulation and was used to deliver umeclidinium (UMEC)/vilanterol (VI) to patients with chronic obstructive pulmonary disease (COPD) in multiple phase 3a studies. This twin-strip inhaler may lead to improved patient compliance.

OBJECTIVES

1. To determine if the COPD patients could use ELLIPTA™ easily (studies DB2114417, DB2114418).
2. To determine if patients preferred ELLIPTA™ when compared with the HandiHaler®† (Studies DB2113360, DB2113374).

METHODS

Clinical studies included

In two 3-month crossover exercise studies (DB2114417, DB2114418; poster #P761(1)) patient use of ELLIPTA™ (Figure 1) was observed. Ease of use and ease of determination of the number of doses left in ELLIPTA™ were collected using two patient questionnaires.

The COPD Device Preference Questionnaire (CDPQ) was administered at the final visit in two 6-month studies (DB2113360, DB2113374) with blinded, double-dummy designs where both ELLIPTA™ and HandiHaler® were used by all patients (DB2113374 poster #P3640(2)).

Objective 1: ELLIPTA™ use assessment and ease of use assessment (Studies DB2114417, DB2114418)

ELLIPTA™ use and ease of use were assessed in the first treatment period of these crossover studies. At randomisation, patients were trained in the correct use of ELLIPTA™, using the instructions provided in the patient information leaflet. Placebo inhalers were used for demonstration in the training assessment.

In the study protocols the correct use of the ELLIPTA™ involved three steps:

- Open the inhaler
- Inhale the dose
- Close the inhaler

Following demonstration of correct use, the patient's competence with a demonstration inhaler was assessed. If the patient did not use the inhaler correctly, then further instruction was given before assessing patient competence again. The demonstration of the inhaler was repeated up to a maximum of three times until the patient could use the inhaler correctly. Patients not able to use the inhaler correctly after three demonstrations were ineligible to enter the study.

Correct inhaler use was re-assessed after 6 weeks of treatment using the demonstration inhaler, without further verbal instruction or demonstration to the patient. If the patient did not perform the manoeuvres correctly, the entire procedure would be once again demonstrated. At each assessment visit, the number of times that the patient required additional instruction was recorded.

The person providing training and assessing correct use of the inhaler was the same individual, where possible, for each patient.

Ease of use assessment

After 6 weeks of treatment, patients were asked to rate the ease of use of the inhaler by answering the following questions:

How do you rate the ease of use of the inhaler?

How easily are you able to tell how many doses of medication are left in the inhaler?

For each of the questions, answers were recorded using a 5-point difficulty scale: (1) very easy; (2) easy; (3) neutral; (4) difficult; and (5) very difficult.

ELLIPTA™ is a trademark of the GlaxoSmithKline group of companies
†HandiHaler® is a trademark of Boehringer Ingelheim

Objective 2: Inhaler preference (Studies DB2113360, DB2113374)

The CDPQ was developed to assess inhaler preference for use in studies DB2113360 and DB2113374. Draft items were based on aspects of ease of use identified by patients and physicians and included questions on the number of steps and time needed to use the inhaler and overall preference.(3)

Two iterative rounds of cognitive interviews were conducted with 8 patients with COPD in each round, to refine the items and assess the content validity of the CDPQ. Participants were recruited using pre-specified criteria including: age ≥40 years, current or past COPD diagnosis, smoking history of ≥10 pack-years, no requirement for oxygen outside the home, ability to provide informed consent and read, understand, and provide responses in English and willingness to participate in a 1-hour interview.

Each participant reviewed and provided feedback on the instructions, items and response options. In the first round participants provided feedback on their preferred phrasing of the draft CDPQ and suggestions for improvement. The CDPQ was modified based on these responses. During Round 2 interviews, participants assessed the modified CDPQ and provided additional input to confirm the content validity of the final version (Table 1).

The CDPQ was administered at the final visit in two 6-month studies (DB2113360, DB2113374) with blinded, double-dummy designs where both ELLIPTA™ and HandiHaler® were used by all patients (DB2113374 poster #P3640(2)). A double-dummy design was used for the active-comparator studies because these studies included delivery with the ELLIPTA™ DPI and the HandiHaler® DPI. Blister-packaged capsules of tiotropium (TIO) or its corresponding placebo were administered once daily in the morning via the HandiHaler® DPI and UMEC/VI, UMEC, VI or placebo were administered once daily in the morning via the ELLIPTA™ DPI. Each patient took one dose from the HandiHaler® DPI and one dose from the ELLIPTA™ DPI each morning. Blinding of TIO was imperfect, however, because the TIO capsules had trade markings but the placebo capsules, while closely matched in colour, did not have trade markings. Whether patients would notice, and rightly or wrongly attach any significance to the capsule markings, is unclear. As these studies were of parallel group design, the capsule type was consistent for each patient for the duration of the study. Both the TIO and placebo blister packages were covered with opaque over-labels with the intent of shielding information appearing on the blister packaging of TIO. The HandiHaler® DPIs were covered with labels in order to mask identifying marks on the inhaler. Dosing in the clinic was administered without the presence of staff involved with safety and efficacy assessments to guard against the possibility that they would observe and draw correct inferences from the presence or absence of markings on capsules removed from the blisters.

FIGURE 1. ELLIPTA™

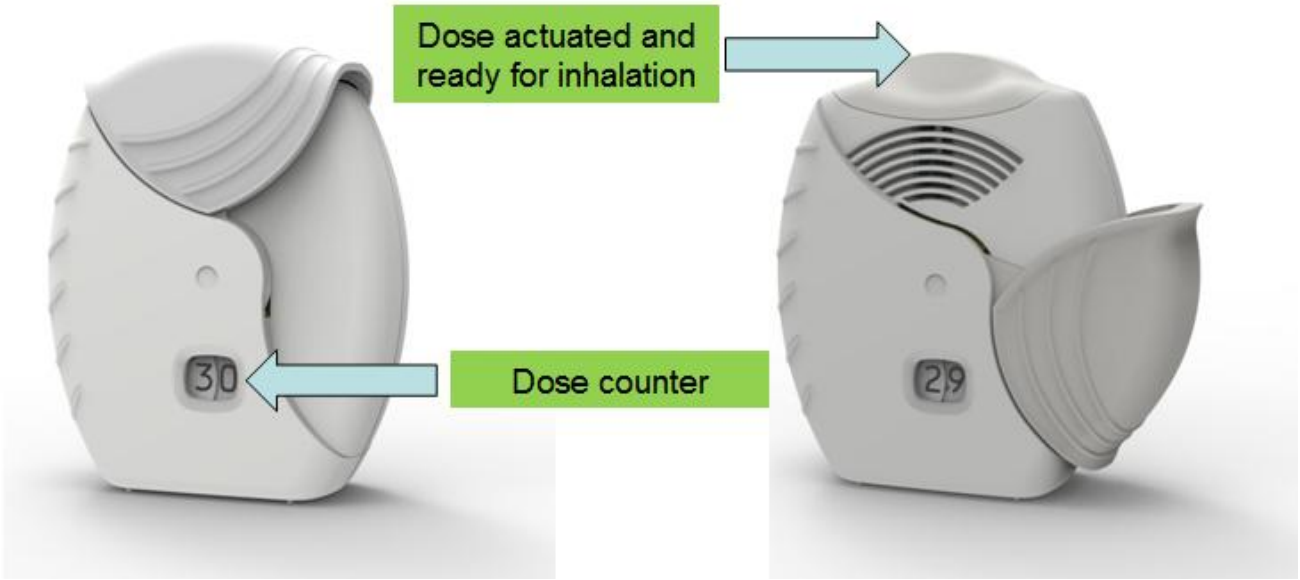

TABLE 1. CDPQ

COPD Device Preference Questionnaire

INSTRUCTIONS: Please complete the following questions related to both the Novel dry powder inhaler and Handihaler devices that you used during this study. Check only one response for each question.

1. Which device do you prefer based on the number of steps needed to take your COPD medication?	o Handihaler device o Novel dry powder inhaler device o No preference
2. Which device do you prefer based on the time needed to take your COPD medication?	o Handihaler device o Novel dry powder inhaler device o No preference
3. Which device do you prefer based on how easy the device is to use?	o Handihaler device o Novel dry powder inhaler device o No preference

RESULTS

Objective 1

Following initial instruction on how to use the inhaler in each of the two exercise studies, 98% of patients used ELLIPTA™ correctly at Day 1 (Table 2). Only one patient failed to use the inhaler correctly after a series of three demonstrations in Study DB2114418. The remaining patients required one further demonstration. Six weeks later when inhaler usage was reassessed, 98—99% of subjects used their ELLIPTA™ DPI correctly (Table 2).

TABLE 2. ELLIPTA™ CORRECT USE OF INHALER

	Response	DB2114417 Total	DB2114418 Total
Visit		N=348	N=307
Day 1	**n**	348	284
Used correctly	**Yes, n (%)**	341 (98)	277 (98)
	No, n (%)	7 (2)	7 (2)
	Missing, n (%)	0 (0)	0 (0)
Week 6	**n**	327	260
Used correctly	**Yes, n (%)**	324 (>99)	256 (98)
	No, n (%)	2 (<1)	4 (2)
	Missing, n (%)	1 (<1)	0 (0)

After 6 weeks of use, a total of 98—99% of patients found the inhaler easy or very easy to use and a minimum of 99% found the dose counter easy or very easy to read (Table 3). No patients found the inhaler very difficult to use.

TABLE 3. ELLIPTA™ EASE OF USE AND REMAINING DOSE DETERMINATION

	Response	DB2114417 Total	DB2114418 Total
		N=348	N=307
Ease of use rating, n (%)	**n**	327	260
	Very easy	227 (69)	206 (79)
	Easy	95 (29)	52 (20)
	Neutral	4 (1)	2 (<1)
	Difficult	1 (<1)	0 (0)
Ease of telling how many doses left, n (%)	**n**	327	260
	Very easy	246 (75)	225 (87)
	Easy	77 (24)	34 (13)
	Neutral	3 (<1)	0 (0)
	Difficult	1 (<1)	1 (<1)

Objective 2

In the 6-month studies (DB2113360, DB2113374), patients consistently stated a greater preference for ELLIPTA™ compared with HandiHaler® with regard to the number of steps to use (59% *vs* 17%), time taken to use (62% *vs* 14%) and overall preference for the inhaler (63% *vs* 15%). These results were consistent regardless of which inhaler contained active drug in these double-dummy studies (Table 4).

TABLE 4. INHALER PREFERENCE

	Combined study results for DB2113360, DB2113374		
	Patients receiving active HandiHaler® N (%)	Patients receiving active ELLIPTA™ N (%)	All patients N (%)
Number of steps			
HandiHaler®	65 (16)	211 (17)	276 (17)
ELLIPTA™	255 (63)	714 (58)	969 (59)
No preference	84 (21)	303 (25)	387 (24)
Time needed to use			
HandiHaler®	44 (11)	181 (15)	225 (14)
ELLIPTA™	268 (66)	749 (61)	1017 (62)
No preference	92 (23)	298 (24)	390 (24)
Ease of Use			
HandiHaler®	52 (13)	199 (16)	251 (15)
ELLIPTA™	260 (64)	760 (62)	1020 (63)
No preference	92 (23)	269 (22)	361 (22)

CONCLUSIONS

- ELLIPTA™ is easy to use following training and the training is not forgotten.
- The ELLIPTA™ dose counter is easy to read.
- Patients with COPD showed a clear preference for ELLIPTA™ compared with HandiHaler®.
- ELLIPTA™ has the potential to reduce the number of handling errors seen with inhalers and increase compliance.

REFERENCES

(1) Maltais F, *et al*. ERS 2013, #P761. Sunday 8th September, 12:50—14:40, Hall 1-13.
(2) DeCramer M, *et al*. ERS 2013, #P3640. Tuesday 10th September 10:45—12:45, Room 3.8
(3) Clark, M. *et al*. *Value Health* 2011;14(7): A255.

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