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 18, 2016**

INNOVIVA, 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)

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)

(Former name or former address, if changed since last report)

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:

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 7.01. Regulation FD Disclosure.

On May 18, 2016, at the Annual Congress of the American Thoracic Society Conference (the "ATS Conference"), GlaxoSmithKline ("GSK") presented three posters containing information about (i) the impact of vilanterol fluticasone furoate (or their combination) on exacerbations in patients with chronic obstructive pulmonary disease ("COPD") with moderate airflow obstruction, (ii) reported pneumonia events in the Study to Understand Mortality and MorbidITy ("SUMMIT") trial and (iii) the results of a randomized, 12 week study testing ANORO® ELLIPTA® (umeclidinium/vilanterol, 'UMEC/VI') as a Step-Up Therapy from Tiotropium in Moderate Symptomatic COPD. The posters are furnished as Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3 to this Current Report on Form 8-K and are incorporated by reference herein.

The information disclosed in this Item 7.01 is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On May 18, 2016, GSK and Innoviva, Inc. ("Innoviva") announced that GSK presented data at the ATS Conference from the two pre-specified analyses from the SUMMIT trial. The press release relating to this announcement is filed as Exhibit 99.4 to this Current Report on Form 8-K and is incorporated by reference herein.

In addition, on May 18, 2016, GSK and Innoviva announced that GSK presented data at the ATS Conference regarding the results of the investigation of the efficacy and safety of UMEC/VI in patients with moderate COPD who continued to have symptoms while on tiotropium monotherapy 18 mcg. The press release relating to this announcement is filed as Exhibit 99.5 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Poster
99.2	Poster
99.3	Poster
99.4	Press Release dated May 18, 2016
99.5	Press Release dated May 18, 2016

SIGNATURE

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

INNOVIVA, INC.

Date: May 18, 2016

By: /s/ Eric d'Esparbes
Eric d'Esparbes
Chief Financial Officer

A6786 (P16)

Impact of vilanterol, fluticasone furoate, or their combination on exacerbati in COPD patients with moderate airflow obstruction: the SUMMIT trial

Martinez FJ[1,2], Anderson JA[3], Brook RD[2], Celli B[4], Crim C[5], Kilbride S[3], Newby DE[6], Vestbo J[7], Yates JC[5], Calverley PMA[8]

[1]New York-Presbyterian Hospital/Weil Cornell Medical Center, New York, NY, USA; [2]University of
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[7]University of Manchester and South Manchester University Hosp

Background

- Long-acting beta agonists (LABAs), inhaled corticosteroids (ICSs), and their combination (ICS/LABA) have been shown to decrease exacerbations of chronic obstructive pulmonary disease (ECOPD) in patients with severe chronic airflow obstruction. Their efficacy in reducing ECOPD in patients with moderate chronic airflow obstruction remains unclear.
- SUMMIT was a prospective, multicenter, randomized, double-blind trial in 16,485 patients with moderate COPD who had, or were at high-risk for, cardiovascular disease; the primary objective was to evaluate the impact of fluticasone furoate (FF)/ vilanterol (VI) on all-cause mortality.

Aims

- The current analysis evaluated the impact of treatment on moderate-to-severe ECOPD, hospitalized ECOPD, and ECOPD requiring systemic corticosteroids (SCS), which were all predefined endpoints of SUMMIT.

Methods

- Eligible patients were current or former smokers, aged 40–80 years with a post-bronchodilator forced expiratory volume in 1 second (FEV_1) ≥50% and ≤70% of the predicted value, a ratio of post-bronchodilator FEV_1 to forced vital capacity ≤0.70, and ≥2 on the modified Medical Research Council dyspnea scale.
- Patients had a history of cardiovascular disease (coronary artery disease, peripheral arterial disease, stroke, myocardial infarction, or diabetes mellitus with target organ disease) or increased cardiovascular risk (≥60 years and receiving medication for ≥2 of the following: hypercholesterolemia, hypertension, diabetes mellitus, or peripheral arterial disease).
- LABAs and ICSs were discontinued at least 48 hours prior to study entry.
- All patients were randomized to receive one of the following (once daily):
  - placebo, FF 100µg, VI 25µg, or FF/VI 100/25µg.
- The rate of ECOPD was analyzed using a negative binomial model, with the logarithm of time on treatment as an offset variable, and covariates of age, gender, and the number of exacerbations reported in the 12 months prior to screening (0, 1, ≥2):
  - moderate/severe ECOPD (requiring treatment with antibiotics and/or SCS or requiring hospitalization), ECOPD requiring hospitalization, and ECOPD requiring SCS.

Results

Patients

- Most patients were middle-aged (65 ± 8 years) men (75%), with 47% active smokers and a mean post-bronchodilator FEV_1 60% of the predicted value (interquartile range 54–65%; **Table 1**).
- In the 12 months prior to study entry, 39% of patients had experienced ECOPD while 15% had suffered two or more episodes.

Mortality

- All-cause mortality (primary endpoint) was not significantly affected by combined FF/VI therapy (hazard ratio vs placebo 0.88, 95% confidence interval [CI]: 0.74–1.04; p=0.14) or the individual treatment components.

Table 1. Selected baseline characteristics in SUMMIT (n=16,485)

	Placebo n=4111	FF n=4135	VI n=4118	FF/VI n=4121
Mean age, years ± SD	65 ± 8	65 ± 8	65 ± 8	65 ± 8
Male, n (%)	3071 (75)	3053 (74)	3053 (74)	3112 (76)
Current smokers, n (%)	1936 (47)	1945 (47)	1929 (47)	1868 (45)
Smoking history, pack-years ± SD	41 ± 25	41 ± 24	41 ± 24	40 ± 24
Post-bronchodilator FEV_1, L ± SD	1.70 ± 0.40	1.70 ± 0.41	1.70 ± 0.40	1.70 ± 0.40
Predicted post-bronchodilator FEV_1, % ± SD	59.7 ± 6.1	59.6 ± 6.1	59.7 ± 6.1	59.7 ± 6.1
FEV_1 reversibility* ± SD	8.4 ± 12.1	7.9 ± 11.7	8.3 ± 12.2	8.0 ± 11.8
Prior COPD therapy, n (%)				
LABA	1417 (34)	1432 (35)	1464 (36)	1456 (35)
LAMA	659 (16)	619 (15)	634 (15)	638 (15)
ICS	1349 (33)	1369 (33)	1374 (33)	1394 (34)
Exacerbations in 12 months pre-study, n (%)				
0	2447 (60)	2546 (62)	2500 (61)	2528 (61)
1	1044 (25)	990 (24)	988 (24)	998 (24)
2+	620 (15)	599 (14)	630 (15)	595 (14)

*As a percentage of pre-bronchodilator FEV_1
LAMA, long-acting muscarinic-agonist; SD, standard deviation

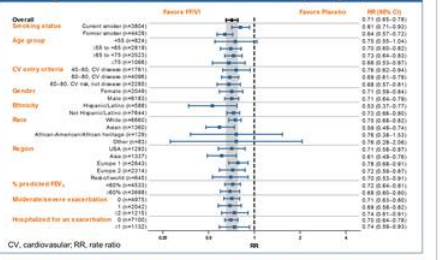
Table 2. Treatment effect on exacerbations

	Placebo n=4111	FF n=4135	VI n=4118	FF/VI n=4121
Moderate/severe ECOPD				
Reduction in risk of first ECOPD, % (95% CI)		3 (-5–10)	9 (1–16)	21 (14–27)
p-value (vs placebo)		0.470	0.023	<0.001
Annual ECOPD rate	0.35	0.31	0.31	0.25
Reduction in ECOPD rate, % (95% CI)		12 (4–19)	10 (2–18)	29 (22–35)
p-value (vs placebo)		0.004	0.017	<0.001
ECOPD requiring hospitalization				
Reduction in risk of first ECOPD, % (95% CI)		12 (-2–25)	15 (2–27)	22 (8–33)
p-value (vs placebo)		0.086	0.031	0.002
Annual ECOPD rate	0.07	0.06	0.06	0.05
Reduction in ECOPD rate, % (95% CI)		18 (3–31)	20 (5–32)	27 (13–39)
p-value (vs placebo)		0.023	0.013	<0.001
ECOPD requiring SCS				
Reduction in risk of first ECOPD, % (95% CI)		15 (6–23)	14 (5–22)	35 (27–41)
p-value (vs placebo)		0.002	0.003	<0.001
Annual ECOPD rate	0.23	0.17	0.19	0.13
Reduction in ECOPD rate, % (95% CI)		25 (15–33)	18 (8–27)	45 (38–52)
p-value (vs placebo)		<0.001	<0.001	<0.001

Exacerbations

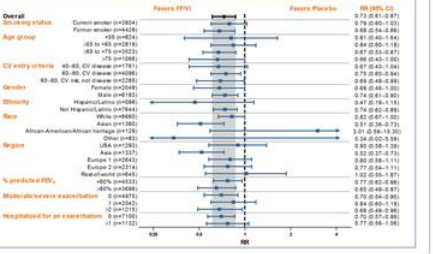
- Compared with placebo, the risk of a first moderate/severe ECOPD was decreased 21% by combined FF/VI treatment (95% CI: 14–27) and 9% by VI (95% CI: 1–16), but not by FF (3% reduction, 95% CI: -5–10; **Table 2**).
- All therapies led to a reduction in the rate of moderate to severe ECOPD (FF/VI 29%, VI 10%, and FF 12%; **Table 2**).
- All therapies also led to a reduction in the rate of ECOPD requiring hospitalization (FF/VI 27%, VI 20%, and FF 18%), or SCS (FF/VI 45%, VI 18%, and FF 25%) compared with placebo (**Table 2**).

Figure 1. Rate of moderate/severe ECOPD by subgroups



CV, cardiovasular; RR, rate ratio

Figure 2. Rate of hospitalized ECOPD by subgroups



A3575 (P994)

Reported pneumonia events in the SUMMIT trial

Crim C[1], Anderson JA[2], Brook RD[3], Calverley PMA[4], Celli B[5], Kilbride S[2], Martinez FJ[6], Newby DE[7], Yates J[1], Vestbo J[8]

*[1]GSK, Research Triangle Park, NC, USA; [2]GSK, Uxbridge, UK; [3]University of Michigan Health S [5]Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; [6]New York P [7]University of Edinburgh, Edinburgh, UK; [8]University of Manchester and South

Aims

- Patients with chronic obstructive pulmonary disease (COPD) are at increased risk for pneumonia. Previous studies have shown that pneumonia risk in COPD is partly related to the severity of airflow limitation.
- For patients receiving inhaled corticosteroid (ICS)-containing regimens, the risk of pneumonia is increased in those with severe (forced expiratory volume in 1 second [FEV_1] ≥30% and <50% predicted) and very severe (FEV_1 <30% predicted) airflow obstruction.
- The Study to Understand Mortality and MorbidITy in COPD (SUMMIT) investigated the effects of an ICS, a long-acting β-agonist (LABA), and the combination in patients with moderate COPD who had, or were at high risk for, cardiovascular disease (CVD).
- The risk of pneumonia in patients with COPD receiving an ICS, a LABA, or the combination was assessed as a safety endpoint in SUMMIT.

Methods

- SUMMIT was a prospective, double-blind, parallel-group, placebo-controlled, event-driven, randomized trial (1368 centers; 43 countries).
- Participants were current or former smokers aged 40–80 years, with a history of COPD and a post-bronchodilator FEV_1 ≥50 and ≤70% of the predicted value, a post-bronchodilator FEV_1/forced vital capacity ≤0.70, and ≥2 on the modified Medical Research Council dyspnea scale.
- Patients had a history of CVD (coronary artery disease, peripheral arterial disease, prior stroke or myocardial infarction, or diabetes mellitus with target organ disease) or increased cardiovascular risk (≥60 years and receiving medications for ≥2 of the following: hypercholesterolemia, hypertension, diabetes mellitus, or peripheral vascular disease).
- ICS and LABA treatments were discontinued before study entry. Participants were then randomized to receive one of the following (once daily):
  - placebo
  - fluticasone furoate (FF) 100µg
  - vilanterol (VI) 25µg
  - FF/VI 100/25µg.
- Adverse events (AEs) were collected at each study visit by the study investigators and coded using the Medical Dictionary for Regulatory Activities (MedDRA® version 18.0; International Federation of Pharmaceutical Manufacturers and Associations, Geneva, Switzerland).
- Treatment effect on the risk of pneumonia was assessed by comparing the incidence, rate, and Kaplan Meier curves for pneumonia.
- Adverse events of special interest (AESIs) were those associated with the known pharmacologic action of ICS or LABA therapy. For pneumonia, this used a pre-defined list of preferred terms from MedDRA that allowed a comprehensive review of pneumonia data (**Table 1**).
- Rate represents the number of events per 100 subject-years of exposure, calculated as: (total number of AEs*100)/total duration of exposure in years.

Table 1. Listing of AE preferred terms for pneumonia events in SUMMIT

Pneumonia	Tuberculosis	Lung consolidation	Pneumonia moraxella
Lobar pneumonia	Pneumonitis	Pneumonia streptococcal	Pneumonia staphylococcal
Bronchopneumonia	Pneumonia aspiration	Empyema	Pneumonia viral
Pulmonary tuberculosis	Pneumonia bacterial	Pneumonia klebsiella	Tuberculous pleurisy
Lung infection	Pneumonia haemophilus		

Results

Participants

- 16,568 patients underwent randomization and took study medication to be included in the safety population.
- Baseline characteristics were balanced across all treatment arms (**Table 2**).

Pneumonias

- Total exposure to study medication was higher in the FF/VI treatment group compared with FF and VI treatment groups, and placebo.
- The incidence and rates of pneumonia AEs and pneumonia serious AEs (SAEs) were comparable in the FF-containing groups and placebo (**Table 3**).
- On-treatment and post-treatment fatal pneumonia SAEs occurred in <1% of patients in all treatment groups (**Table 3**).
- Treatment did not increase the rate of adjudicated on-treatment deaths compared with placebo (**Table 3**).

Table 2. Selected screening characteristics in SUMMIT (safety population)

	Placebo n=4131	FF 100µg n=4157	VI 25µg n=4140	FF/VI 100/25µg n=4140
Mean age, years ± SD	65 ± 8	65 ± 8	65 ± 8	65 ± 8
Male, n (%)	3081 (75)	3059 (74)	3069 (74)	3121 (75)
BMI, kg/m² ± SD	28 ± 6	28 ± 6	28 ± 6	28 ± 6
Current smokers, n (%)	1949 (47)	1952 (47)	1941 (47)	1875 (45)
Smoking history, pack-years ± SD	41 ± 25	41 ± 24	41 ± 24	40 ± 24
Predicted post-bronchodilator FEV_1, % ± SD	60 ± 6	60 ± 6	60 ± 6	60 ± 6
Pre-study COPD therapy, %				
LABA	35	35	36	35
LAMA	16	15	15	15
ICS	33	33	33	34

BMI, body mass index; LABD, long-acting bronchodilator; LAMA, long-acting muscarinic antagonist; SD, standard deviation. Combination products are included in all applicable respiratory medication classes.

Table 3. Summary of pneumonias in safety population

	Placebo n=4131	FF 100µg n=4157	VI 25µg n=4140	FF/VI 100/25µg n=4140
Total exposure to study medication, years	6614	6889	6955	7038
Pneumonia terms*				
Patients with on-treatment AEs	214 (5%)	228 (5%)	163 (4%)	237 (6%)
Rate (number of AEs)	3.84 (254)	4.24 (292)	2.77 (193)	3.95 (278)
Patients with on-treatment SAEs	127 (3%)	146 (4%)	104 (3%)	140 (3%)
Rate (number of AEs)	2.22 (147)	2.51 (173)	1.64 (114)	2.24 (158)
Patients with on and post-treatment fatal SAEs	16 (<1%)	23 (<1%)	13 (<1%)	23 (<1%)
Patients with on-treatment fatal SAEs	10 (<1%)	17 (<1%)	5 (<1%)	16 (<1%)
Rate (number of AEs)	0.15 (10)	0.25 (17)	0.07 (5)	0.23 (16)
Patients with post-treatment fatal SAEs	6 (<1%)	6 (<1%)	8 (<1%)	7 (<1%)
Pneumonia death†				
Total deaths	16 (<1%)	19 (<1%)	13 (<1%)	24 (<1%)
On-treatment deaths	9 (<1%)	10 (<1%)	6 (<1%)	13 (<1%)
Rate of on-treatment deaths	0.14	0.15	0.09	0.18

*Terms from the AESI grouping of pneumonia. Includes one SAE that was not fatal in the FF arm with verbatim term of 'non pulmonary tuberculosis' that coded to preferred term tuberculosis
†Cause of death as adjudicated by the Clinical Endpoint committee. This includes the following classifications: pulmonary (COPD with pneumonia) and other (pneumonia)

Time to pneumonia AEs

- There was no difference in the time to first on-treatment AE or SAE in the FF-containing treatment groups compared with placebo (**Figure 1**).

Presented at the ATS International Conference, San Francisco, CA, USA, 13–18 May 2016

UMEC/VI as Step-Up Therapy from Tiotropium in Moderate Symptomatic C
a Randomized, 12-Week Study

Poster No: P27 (A6797)

Kerwin E[1], Kalberg CJ[2], Galkin D[2], Zhu C-Q[3], Church A[2], Fahy WA[4]

[1]Clinical Research Institute of Southern Or
Research Triangle Park, NC, USA; [3]Clinical Statistics, GSK, Uxbridge, Middlese

Introduction

- Bronchodilators, including long-acting muscarinic antagonists (LAMAs) and long-acting β_2-agonists (LABAs), are a mainstay in the pharmacological management of stable chronic obstructive pulmonary disease (COPD).[1]
- Despite the benefits associated with LAMAs,[2] many patients receiving LAMA monotherapy fail to achieve optimal disease control.[3] It has therefore been proposed that step-up to a combined LAMA/LABA therapy may improve lung function and reduce symptoms in these patients.
- The once-daily LAMA/LABA umeclidinium/vilanterol (UMEC/VI; 62.5/25 mcg/day) has been widely approved as a maintenance treatment for COPD.[4]
- This study evaluated the efficacy and safety of stepping up patients with moderate COPD with at least mild dyspnea from the LAMA tiotropium (TIO) to UMEC/VI dual bronchodilator therapy compared with remaining on TIO monotherapy.

Methods

Study design

- Randomized, blinded, double-dummy, parallel-group study (NCT01899742; GSK identifier: 116960) performed over 12 weeks in 9 countries.
- Patients completed a 4-week run-in period on open-label TIO before randomization.

Inclusion/exclusion criteria

- Patients: were ≥40 years of age with a diagnosis of COPD; had a ≥10-pack-year smoking history; had a forced expiratory volume in 1 second (FEV_1)/forced vital capacity ratio of <0.70; had a post-albuterol FEV_1 of ≤70% and ≥50% of predicted values (Global initiative for chronic Obstructive Lung Disease [GOLD] classification II)[1]; had a modified Medical Research Council (mMRC) Dyspnea Scale score of ≥1; and were prescribed TIO for ≥3 months prior to screening. A mMRC score ≥1 after run-in was also required.
- Exclusions included other clinically significant respiratory diseases including asthma; use of inhaled corticosteroids or maintenance COPD medication other than TIO in the 3 months prior to screening; and ≥2 moderate/severe COPD exacerbations in the past 12 months.

Treatment

- Patients received either once-daily UMEC/VI 62.5/25 mcg (delivering 55/22 mcg) via the ELLIPTA™ inhaler and placebo via the HandiHaler®, or once-daily TIO 18 mcg via the HandiHaler® and placebo via the ELLIPTA™ inhaler for 12 weeks.
  - Blinding was performed through color-matching of capsules and opaque overlabels of blister packaging.

Outcomes

- The primary endpoint was trough FEV_1 at Day 85.
- Additional endpoints included: serial FEV_1 assessments 0–3 h post dose; Transition Dyspnea Index (TDI) scores, rescue medication use, St George's Respiratory Questionnaire (SGRQ) score, and COPD Assessment Test (CAT) score.
- Safety evaluations included adverse events (AEs) and COPD exacerbations.
- A subset of patients (the 24-h [TFH] population) participated in serial spirometry measurements over 24 h on Days 1 and 84.

Results

Demographics

- Of the 739 enrolled patients, 494 were randomized to UMEC/VI or TIO (the intent-to-treat [ITT] population, n=247 in each treatment group). Most screen failures (82%) did not meet the percentage predicted FEV_1 requirement.
- Both groups had similar demographics and baseline characteristics (**Table 1**).

Table 1. Patient demographics and baseline characteristics (ITT population)

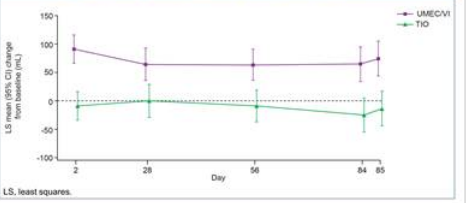
	UMEC/VI (N=247)	TIO (N=247)
Age, years	64.5 (8.7)	64.3 (8.7)
Sex, male, n (%)	163 (66)	160 (65)
Current smoker, n (%)	129 (52)	118 (48)
Smoking pack years	38.6 (20.5)	40.4 (20.2)
FEV_1, L[a]	1.715 (0.471)	1.673 (0.443)
Percent predicted FEV_1, %	59.8 (5.5)	59.4 (5.3)
mMRC dyspnea score at screening	1.9 (0.6)	1.8 (0.6)
mMRC dyspnea score at randomization	1.8 (0.6)	1.8 (0.6)
GOLD category (mMRC criteria), %		
A/B	23/65	27/59
C/D	1/11	1/13
Rescue medication use, puffs/day[b]	1.1 (1.4)	1.2 (1.8)
BDI focal score at Day 1[c]	6.5 (1.3)	6.5 (1.4)
SGRQ total score at Day 1[d]	41.3 (14.4)	42.3 (14.8)
CAT score at Day 1	16.7 (6.2)	16.4 (6.5)

[a]Mean value of assessments 23 and 24 h post dose prior to Day 1 (both groups on TIO); [b]calculated from the mean number of puffs between the first day [the latest of 27 days before Visit 2 and the day after Visit 1] and the day of Visit 2; [c]UMEC/VI, n=240; TIO, n=245; [d]UMEC/VI, n=242; TIO, n=245. BDI, baseline dyspnea index. Data reported at screening unless otherwise stated. Values are reported as mean (SD) unless otherwise stated.
SD, standard deviation.

Lung function outcomes

- UMEC/VI produced statistically significant improvements in trough FEV_1 versus TIO at Day 85 (difference: 88 mL; 95% confidence interval [CI]: 45, 131; p<0.001) and all other time points (**Figure 1**).

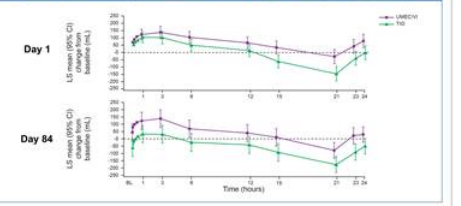
Figure 1. Change from baseline in trough FEV_1 (ITT population)



LS, least squares.

- On Days 1 and 84, UMEC/VI produced a statistically significant improvement in FEV_1 at 3 h post dose (73 mL; 95% CI: 24, 122; p=0.004 on Day 84) and at all other post-dose time points as early as 5 min versus TIO.
- Serial FEV_1 measurements 0–24 h post dose (TFH subpopulation: UMEC/VI, n=94; TIO, n=92) demonstrated that UMEC/VI gave statistically significant improvements in 0–24 h weighted mean FEV_1 compared with TIO at Days 1 (69 mL; 95% CI: 20, 118; p=0.006) and 84 (102 mL; 95% CI: 28, 176; p=0.007) (**Figure 2**).

Figure 2. Serial FEV_1 measurements 0–24 h post dose (TFH population)



TDI score, patient-reported outcomes, and rescue medication use

- At Day 84, clinically meaningful improvements in TDI, SGRQ, and CAT scores from baseline were seen in both treatment groups with no statistically significant differences between the groups (**Table 2**).
- UMEC/VI significantly increased the odds of being a TDI responder (defined as a ≥1-unit improvement) versus a non-responder compared with TIO on Days 28 and 84 (**Figure 3**).
- UMEC/VI resulted in a statistically significant reduction in rescue medication use compared with TIO (-0.1 puffs/day over 1–12 weeks; 95% CI: -0.2, 0.0; p=0.027).
- UMEC/VI resulted in a greater increase in the percentage of rescue-free days compared with TIO (median difference: 2.3 days; 95% CI: 0.0, 4.8; p<0.01).

Table 2. TDI score, patient-reported outcomes and rescue medication use at Day 84

		UMEC/VI	TIO
TDI score[a]			
	LS mean (SE)	2.3 (0.16)	1.9 (0.16)
	Difference (95% CI)	0.4 (-0.1, 0.8; p=0.083)	
SGRQ total score[b]			
	LS mean change from baseline (SE)	-4.41 (0.68)	-4.21 (0.67)
	Difference (95% CI)	-0.20 (-2.09, 1.68; p=0.834)	
CAT score[c]			
	LS mean change from baseline (SE)	-2.10 (0.36)	-1.84 (0.35)
	Difference (95% CI)	-0.26 (-1.25, 0.72; p=0.603)	
Rescue medication use (puffs/day, Weeks 1–12)			
	LS mean change from baseline (SE)	-0.3 (0.04)	-0.2 (0.04)
	Difference (95% CI)	-0.1 (-0.2, 0.0; p=0.027)	

[a]UMEC/VI, n=226; TIO, n=233; [b]UMEC/VI, n=225; TIO, n=232; [c]UMEC/VI, n=233; TIO, n=235. SE, standard error.

Presented at the Annual Congress of the American Thoracic Society (ATS), San Francisco, CA, USA, May 13–18, 2016

PRESS RELEASE

Issued: Wednesday 18th May 2016

GSK present new data from Breo® Ellipta® SUMMIT study in patients with COPD at ATS Conference

GlaxoSmithKline (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced that GlaxoSmithKline plc (GSK) presented new data at the American Thoracic Society (ATS) Conference from two pre-specified analyses from the Study to Understand Mortality and MorbidITy (SUMMIT) trial. One demonstrated that patients with Chronic Obstructive Pulmonary Disease (COPD) and moderate airflow limitation receiving Breo® Ellipta® (fluticasone furoate/vilanterol or FF/VI 100/25mcg) achieved improvements in exacerbations compared with placebo. The second analysis demonstrated these patients reported similar rates of pneumonia when taking FF/VI 100/25mcg compared with placebo.

The SUMMIT trial was designed to evaluate the effect of FF/VI 100/25mcg once-daily on all-cause mortality compared with placebo in patients with moderate COPD who had, or were at high risk for Cardiovascular Disease (CVD). Results of the primary endpoint were announced in 2015 and showed that all cause mortality was not affected by combination therapy or the individual components.

The first analysis presented investigated the impact of FF/VI 100/25mcg, an inhaled corticosteroid/long-acting beta$_2$ agonist combination (ICS/LABA), on exacerbations in COPD patients with moderate airflow limitation (mean FEV_1 60% predicted). In patients treated with FF/VI 100/25mcg the risk of a COPD exacerbation, measured by time to first exacerbation, was decreased by 20% (HR 0.80, 95% confidence interval 0.73 — 0.86) versus placebo. In addition, FF/VI 100/25mcg led to a 29% reduction in the rate of a moderate to severe exacerbation of COPD compared with placebo.

A second analysis of all reported pneumonia events amongst the 16,568 patients in the SUMMIT trial showed that rates were similar for patients randomised to FF/VI 100/25mcg compared with those on placebo. Reported pneumonia related adverse-events on FF/VI 100/25mcg were 6% compared with placebo 5%, reported pneumonia related serious adverse-events on FF/VI 100/25mcg were 3% compared with placebo 3%.

Dr Courtney Crim, Director Clinical Development, R&D Respiratory, GSK said: “We believe these data are important for COPD physicians and are clinically relevant. These findings from SUMMIT show that COPD patients with moderate airflow limitation experienced both a lower risk of having an exacerbation and fewer exacerbations when treated with FF/VI than patients on placebo. In the same patients with moderate airflow limitation we also saw a similar incidence of pneumonia in patients on FF/VI and those on placebo. In previous studies, in more severe patients, an increase in the incidence of pneumonias has been observed in ICS-containing treatment arms. The finding from this study is therefore interesting and will require further investigation.”

These data were presented at the ATS 2016 Conference 13 — 18 May, San Francisco, US:

F.J. Martinez, et al. The impact of vilanterol, fluticasone furoate, or their combination on exacerbations in COPD patients with moderate airflow obstruction: the SUMMIT trial. D36-COPD: LABA, LAMA, ICS, AND COMBINATIONS, Thematic Poster Session. Wednesday, May 18, 2016. 9:00 AM-3:30 PM

C. Crim, et al. Reported Pneumonia Events in the SUMMIT trial. B44-COPD: COMORBIDITIES. Thematic Poster Session. Monday May 16, 2016. 9:00 AM-4:15 PM

About the SUMMIT Study

SUMMIT is an international, multi-centre, placebo-controlled, double blind, randomised, parallel group trial designed to determine the impact of FF/VI 100/25 (fluticasone furoate/vilanterol or FF/VI) on the survival of COPD patients with moderate airflow limitation and a history of or increased risk of cardiovascular disease (CVD).

COPD patients with moderate airflow limitation ($\geq$50 and $\leq$70% predicted FEV_1) and a history or risk of CVD were randomised 1:1:1:1 to one of four double-blind treatment groups: FF/VI 100/25mcg, FF 100mcg, VI 25mcg or placebo. All treatments were administered once daily via the Ellipta dry powder inhaler.

The study showed a 12.2% reduction in the risk of dying from any cause for patients who were treated with FF/VI 100/25mcg when compared with those who received placebo (p=0.137). This did not achieve statistical significance.

The impact of vilanterol, fluticasone furoate, or their combination on exacerbations in COPD patients with moderate airflow obstruction and the reported pneumonia events in the SUMMIT trial, were pre-specified analyses. As the primary endpoint of the SUMMIT was not met, statistical significance cannot be inferred from the results of these newly-published analyses.

The study is listed on www.clinicaltrials.gov (NCT01313676).

About COPD and CVD

Chronic Obstructive Pulmonary Disease (COPD) is a disease of the lungs that includes chronic bronchitis, emphysema or both. COPD is characterised by obstruction to airflow that interferes with normal breathing. Cigarette smoke, breathing in second-hand smoke, air pollution including biomass fuels, chemical fumes and dust from the environment or workplace can all contribute to COPD.

COPD mortality is increasing and is the third leading cause of death globally. COPD often coexists with other chronic diseases and epidemiological data suggests that CVD or CV risk occurs in nearly half of all patients with COPD. CVD is the number one killer of mild to moderate COPD patients and patients with both COPD and CVD or CV risk were observed to have a mortality rate double that of COPD patients without CVD in studies of up to 15 years in duration.

About FF/VI 100/25mcg

FF/VI 100/25mcg, under the brand name Breo® Ellipta® 100/25mcg is licensed in the US for:

- the long-term, once-daily, maintenance treatment of airflow obstruction in patients with Chronic Obstructive Pulmonary Disease (COPD), including chronic bronchitis and/or emphysema and to reduce exacerbations of COPD in patients with a history of exacerbations. Breo® Ellipta® 100/25mcg is the only strength indicated for the treatment of COPD.
- Breo Ellipta100/25mcg is not indicated for the relief of acute bronchospasm.

Full US prescribing information, including BOXED WARNING and Medication Guide is available at us.gsk.com or US Prescribing Information Breo Ellipta.

FF/VI 100/25mcg, under the brand name Relvar® Ellipta® is approved in Europe for:

- the symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a FEV_1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.

For the EU Summary of Product Characteristics for Relvar Ellipta, please visit: http://ec.europa.eu/health/documents/community-register/html/h886.htm

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Important Safety Information (ISI) for FF/VI (Breo Ellipta) in the US

The following ISI is based on the Highlights section of the US Prescribing Information for Breo Ellipta. Please consult the full Prescribing Information for all the labelled safety information for Breo Ellipta.

Long-acting beta$_2$-adrenergic agonists (LABA), such as vilanterol, one of the active ingredients in BREO ELLIPTA, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths. This finding with salmeterol is considered a class effect of all LABA. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids (ICS) or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA.

Breo Ellipta is contraindicated for primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required and in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients.

Breo Ellipta should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD or asthma, or used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist.

Breo Ellipta should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medications containing LABAs, as an overdose may result.

Oropharyngeal candidiasis has occurred in patients treated with Breo Ellipta. Patients should be advised to rinse their mouth with water without swallowing after inhalation to help reduce this risk.

An increase in the incidence of pneumonia has been observed in subjects with COPD receiving the fluticasone furoate/vilanterol combination, including Breo Ellipta 100 mcg/25 mcg, in clinical trials. There was also an increased incidence of pneumonias resulting in hospitalisation. In some incidences these pneumonia events were fatal.

Patients who use corticosteroids are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients.

Particular care is needed for patients who have been transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids.

Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage of inhaled corticosteroids in susceptible individuals.

Caution should be exercised when considering the coadministration of Breo Ellipta with long-term ketoconazole and other known strong CYP3A4 inhibitors because increased systemic corticosteroid and cardiovascular adverse effects may occur.

Breo Ellipta can produce paradoxical bronchospasm which may be life-threatening.

Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of Breo Ellipta.

Vilanterol, the LABA in Breo Ellipta, can produce clinically significant cardiovascular effects in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, and also cardiac arrhythmias. Breo Ellipta should be used with caution in patients with cardiovascular disorders.

Decreases in bone mineral density have been observed with long-term administration of products containing inhaled corticosteroids, as have glaucoma, increased intraocular pressure, and cataracts.

Breo Ellipta should be used with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients. Beta-adrenergic agonist medicines may produce transient hyperglycemia in some patients. Orally inhaled corticosteroids may cause a reduction in growth velocity when administered in children and adolescents.

For COPD, the most common adverse reactions (≥3% and more common than in placebo) reported in two 6-month clinical trials with Breo Ellipta 100/25 (and placebo) were nasopharyngitis, 9% (8%); upper respiratory tract infection, 7% (3%); headache, 7% (5%); and oral candidiasis, 5% (2%). In addition to the reactions reported in the 6-month studies, adverse reactions occurring in ≥3% of the subjects treated with Breo Ellipta 100/25 in two 1-year studies included back pain, pneumonia, bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, influenza, pharyngitis, and pyrexia.

GSK — one of the world's leading research-based pharmaceutical and healthcare companies — is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

About Innoviva - Innoviva is focused on bringing compelling new medicines to patients in areas of unmet need by leveraging its significant expertise in the development, commercialization and financial management of bio-pharmaceuticals. Innoviva's portfolio is anchored by the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, which were jointly developed by Innoviva and GSK. Under the agreement with GSK, Innoviva is eligible to receive associated royalty revenues from RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and, if approved and commercialized, VI monotherapy, as well. In addition, Innoviva retains a 15 percent economic interest in future payments made by GSK for earlier-stage programs partnered with Theravance BioPharma, Inc. For more information, please visit Innoviva's website at www.inva.com. RELVAR®, BREO®, ANORO® and ELLIPTA® are trademarks of the GlaxoSmithKline group of companies.

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Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2015.

Innoviva forward-looking statements

This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives and future events. Innoviva intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve substantial risks, uncertainties and assumptions. Examples of such statements include statements relating to: prescription and market share trends, payor coverage, the strategies, plans and objectives of the company, the timing, manner and amount of anticipated potential capital returns to stockholders (including without limitation, expectations of future share repurchases or cash dividends), the status and timing of clinical studies, data analysis and communication of results, the potential benefits and mechanisms of action of product candidates, expectations for products, and projections of revenue, expenses and other financial items. These statements are based on the current estimates and assumptions of the management of Innoviva as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Innoviva to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to: lower than expected future royalty revenue from respiratory products partnered with GSK, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, dependence on third parties to conduct its clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, and risks of collaborating with third parties to discover, develop and commercialize products. Other risks affecting Innoviva are described under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Innoviva's Annual Report on Form 10-K for the year ended December 31, 2015 and Innoviva's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. In addition to the risks described above and in Innoviva's other filings with the SEC, other unknown or unpredictable factors also could affect Innoviva's results. Past performance is not necessarily indicative of future results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Innoviva assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law. (INVA-G)

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PRESS RELEASE

Issued: Wednesday 18th May 2016

GSK presents efficacy data for Anoro® Ellipta® in COPD patients who remained symptomatic on tiotropium

GlaxoSmithKline (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced results from data presented at the American Thoracic Society (ATS) 2016 International Conference investigating the efficacy and safety of Anoro® Ellipta® (umeclidinium/vilanterol, 'UMEC/VI') in patients with moderate chronic obstructive pulmonary disease (COPD) who continued to have symptoms while on tiotropium monotherapy.

For patients in the study who were switched from tiotropium 18mcg to UMEC/VI 62.5/25mcg, a statistically significant improvement of 88mL (P<0.001; 95% CI 45, 131) was shown at week 12 for the primary efficacy endpoint of lung function (measured by trough FEV_1), compared to patients who remained on tiotropium 18mcg for the duration of the study.

For the secondary efficacy endpoint of three hour post-dose FEV_1, a statistically significant improvement in lung function of 73mL (P=0.004; 95% CI 24, 122) was also shown at week 12 for patients who were switched to UMEC/VI 62.5mcg, compared to patients who stayed on tiotropium 18mcg for the duration of the study.

Professor Neil Barnes, Global Respiratory Franchise Medical Head, GSK, said: "For COPD patients who remain symptomatic it is important that their lung function is optimised effectively. These efficacy data demonstrate the improvement in lung function that can be achieved in patients with moderate COPD when changing treatment from monotherapy with tiotropium 18mcg to dual bronchodilation with Anoro Ellipta."

Furthermore, Dr. Ted Witek, Chief Scientific Officer of Innoviva, Inc. said: "This adds to the growing evidence base that shows that use of two mechanistic pathways can help symptomatic patients with COPD to improve their lung function."

The most commonly reported adverse events for both UMEC/VI 62.5/25mcg and tiotropium 18mcg were nasopharyngitis (7% UMEC/VI 62.5/25mcg; 7% tiotropium 18mcg) and headache (6% UMEC/VI 62.5/25mcg; 7% tiotropium 18mcg). The overall incidence of on-treatment adverse events was 30% in the UMEC/VI 62.5/25mcg group and 31% in the tiotropium 18mcg group. The incidence of any on-treatment non-fatal serious adverse event was 2% in the UMEC/VI 62.5/25mcg arm and 2% in the tiotropium 18mcg arm. There was one fatal serious adverse event in the UMEC/VI group which was not related to study medication.

Study Design

The study (DB2116960) was a 12-week, multicentre, randomised, blinded* study designed to compare UMEC/VI 62.5/25mcg once-daily with tiotropium 18mcg once-daily in patients with moderate COPD who continue to have symptoms on tiotropium.

Patients in the study were required to have been prescribed tiotropium 18mcg once-daily for at least 3 months prior to screening and have completed a 4-week run-in on open-label tiotropium prior to randomisation. Patients had to be 'symptomatic' (defined as 50—70% predicted post-bronchodilator forced expiratory volume in one second [FEV_1] with a modified Medical Research Council [mMRC]

**Details of the blinding process for tiotropium can be found on page 474 in Decramer M et al. Lancet Respir Med 2014; 2:472—486.5.*

score of ³1) at screening and at randomisation.

A total of 494 patients were randomised 1:1 to UMEC/VI 62.5/25mcg once-daily administered via the Ellipta inhaler or tiotropium 18mcg once-daily administered via a Handihaler® inhaler and received at least one dose of study medication.

Further details on the study design and the full results for this study can be found on the GSK Clinical Study Register (DB2116960).

About COPD

COPD is a disease of the lungs that includes chronic bronchitis, emphysema or both. COPD is characterised by obstruction to airflow that interferes with normal breathing.(1) COPD is thought to affect 329 million people worldwide.(2)

Long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD. Cigarette smoke, breathing in second hand smoke, air pollution, chemical fumes or dust from the environment or workplace can all contribute to COPD. Most people who have COPD are at least 40 years old when symptoms begin.(3)

About Anoro Ellipta

Anoro Ellipta is a combination long-acting muscarinic antagonist (LAMA) (also known as an anticholinergic) / long-acting $beta_2$-adrenergic agonist (LABA).

In the US, Anoro Ellipta is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. Anoro Ellipta is not indicated for the relief of acute bronchospasm or for the treatment of asthma. The FDA-approved strength is umeclidinium/vilanterol 62.5/25mcg. Full US prescribing information, including BOXED WARNING and Medication Guide are available at: https://www.gsksource.com/gskprm/htdocs/documents/ANORO-ELLIPTA-PI-MG.PDF.

In Europe, Anoro is indicated as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. The approved strength in Europe is UMEC/VI 55mcg/22mcg (delivered dose, equivalent to 62.5mcg/25mcg pre-dispensed dose). For the EU Summary of Product Characteristics (SmPC), please visit: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002751/WC500168424.pdf

Important Safety Information for Anoro Ellipta

The following Important Safety Information (ISI) is based on the Highlights section of the Prescribing Information for Anoro Ellipta. Please consult the full Prescribing Information for all the labelled safety information for Anoro Ellipta.

Long-acting $beta_2$-adrenergic agonists (LABAs), such as vilanterol, one of the active ingredients in Anoro Ellipta, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths in subjects receiving salmeterol. This finding with salmeterol is considered a class effect of all LABAs, including vilanterol. The safety and efficacy of Anoro Ellipta in patients with asthma have not been established. Anoro Ellipta is not indicated for the treatment of asthma.

Anoro Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either umeclidinium, vilanterol, or any of the other ingredients.

Anoro Ellipta should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD, or as rescue therapy for the treatment of acute episodes of bronchospasm, which should be treated with an inhaled, short-acting $beta_2$-agonist.

Anoro Ellipta should not be used more often than recommended, at higher doses than recommended, or in conjunction with additional medicine containing a LABA, as an overdose may result.

Anoro Ellipta should be used with caution when considering coadministration with long-term ketoconazole and other known strong cytochrome P450 3A4 inhibitors because increased cardiovascular adverse effects may occur.

As with other inhaled medicines, Anoro Ellipta can produce paradoxical bronchospasm, which may be life-threatening.

Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of Anoro Ellipta. Discontinue Anoro Ellipta if such reactions occur.

Anoro Ellipta should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Anoro Ellipta should be used with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

Anoro Ellipta should be used with caution in patients with narrow-angle glaucoma. Instruct patients to contact a physician immediately should any signs or symptoms of narrow-angle glaucoma occur.

Anoro Ellipta should be used with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder neck obstruction. Instruct patients to contact a physician immediately should any signs or symptoms of urinary retention occur.

Beta-adrenergic agonist medicines may produce significant hypokalemia and transient hyperglycemia in some patients.

The most common adverse reactions (incidence ≥1% and more common than placebo) reported in four 6-month clinical trials with Anoro Ellipta (and placebo) were pharyngitis, 2% (<1%); sinusitis 1% (<1%); lower respiratory tract infection, 1% (<1%); constipation, 1% (<1%); diarrhea, 2% (1%); pain in extremity 2% (1%); muscle spasms, 1% (<1%); neck pain, 1% (<1%); and chest pain 1% (<1%). In addition to the 6-month efficacy trials with Anoro Ellipta, a 12-month trial evaluated the safety of umeclidinium/vilanterol 125 mcg/25 mcg in subjects with COPD. Adverse reactions (incidence ≥1% and more common than placebo) in subjects receiving umeclidinium/vilanterol 125 mcg/25 mcg were: headache, back pain, sinusitis, cough, urinary tract infection, arthralgia, nausea, vertigo, abdominal pain, pleuritic pain, viral respiratory tract infection, toothache, and diabetes mellitus.

$Beta_2$-agonists, such as vilanterol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists on the cardiovascular system may be potentiated.

Use beta blockers with caution as they not only block the pulmonary effect of $beta_2$-agonists, such as vilanterol, but may produce severe bronchospasm in patients with COPD.

Use with caution in patients taking non—potassium-sparing diuretics, as electrocardiographic changes and/or hypokalemia associated with non—potassium-sparing diuretics may worsen with concomitant beta-agonists.

Avoid co-administration of Anoro Ellipta with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects such as cardiovascular effects, worsening of narrow-angle glaucoma, and worsening of urinary retention.

ANORO® and ELLIPTA® are trade marks of the GlaxoSmithKline group of companies.

HANDIHALER® is a trade mark of the Boehringer Ingelheim group of companies.

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assumptions of the management of Innoviva as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Innoviva to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to: lower than expected future royalty revenue from respiratory products partnered with GSK, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, dependence on third parties to conduct its clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, and risks of collaborating with third parties to discover, develop and commercialize products. Other risks affecting Innoviva are described under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Innoviva's Annual Report on Form 10-K for the year ended December 31, 2015 and Innoviva's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. In addition to the risks described above and in Innoviva's other filings with the SEC, other unknown or unpredictable factors also could affect Innoviva's results. Past performance is not necessarily indicative of future results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Innoviva assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law. (INVA-G)

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