GLAXOSMITHKLINE PLC
Form 6-K
September 08, 2015

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For period ending September 2015

GlaxoSmithKline plc
(Name of registrant)

980 Great West Road, Brentford, Middlesex, TW8 9GS
(Address of principal executive offices)

Indicate by check mark whether the registrant files or
will file annual reports under cover Form 20-F or Form 40-F

Form 20-F x Form 40-F

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Indicate by check mark whether the registrant by furnishing the
information contained in this Form is also thereby furnishing the
information to the Commission pursuant to Rule 12g3-2(b) under the
Securities Exchange Act of 1934.

Yes No x

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Issued: 8 September 2015, London, UK and South San Francisco, CA, USA - LSE announcement

GSK and Theravance announce results from the SUMMIT COPD CV Survival Study

GlaxoSmithKline plc (LSE/NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced initial results from the Study to Understand Mortality and MorbidITy in COPD (SUMMIT) for Relvar®/Breo® Ellipta® 100/25mcg (fluticasone furoate 'FF'/vilanterol 'VI' or 'FF/VI'). The study involved 16,485 patients from 43 countries who had chronic obstructive pulmonary disease (COPD) with moderate airflow limitation (FEV1 50-70% predicted) and either a history or increased risk of cardiovascular disease (CVD).

For the primary endpoint of the study, the risk of dying on FF/VI 100/25mcg was 12.2% lower than on placebo* over the study period, which was not statistically significant (p=0.137).

For the first of two secondary endpoints, FF/VI 100/25mcg reduced the rate of lung function decline (as measured by forced expiratory volume in one second, 'FEV1') by 8mL per year compared with placebo (p=0.019). As the primary endpoint was not met, statistical significance cannot be inferred from this result. For the other secondary endpoint, the risk of experiencing an on-treatment cardiovascular (CV) event (CV death, myocardial infarction, stroke, unstable angina and transient ischemic attack [TIA]) at any time was 7.4% lower in patients taking FF/VI 100/25mcg versus placebo which was not statistically significant (p=0.475).

The study also formally analysed a number of additional COPD endpoints assessing the efficacy of FF/VI relative to placebo, which included FEV1 (post-bronchodilator), rate of moderate/severe exacerbations, time to first moderate/severe exacerbation, time to first severe (hospitalised) exacerbation, rate of severe (hospitalised) exacerbation, health related quality of life (as measured by the St George's Respiratory Questionnaire-COPD total score at 12 months) and health status as measured using the COPD Assessment Tool (CAT) at 12 months. Against these endpoints FF/VI demonstrated an improvement compared to placebo with a nominal P-value of <0.002 for each. As the primary endpoint was not met, statistical significance cannot be inferred from these results.

The most frequently reported adverse events (greater than or equal to 3% in FF/VI 100/25mcg and greater than placebo) were nasopharyngitis (FF/VI 100/25mcg 8.9%, placebo 7.5%), upper respiratory tract infection (FF/VI 100/25mcg 6.3%, placebo 4.8%), pneumonia (FF/VI 100/25mcg 5.0%, placebo 4.6%), back pain (FF/VI 100/25mcg 4.3%, placebo 3.5%), hypertension (FF/VI 100/25mcg 3.9%, placebo 3.3%) and influenza (FF/VI 100/25mcg 3.4%, placebo 2.9%).

The incidence of on-treatment serious adverse events (SAEs) were 23.2% on FF/VI 100/25mcg and 22.2% on placebo. Adverse events of special interest included all related terms for CV adverse events and pneumonia. The incidence of CV adverse events was 17.8% on FF/VI 100/25mcg, 16.8% on placebo and serious CV adverse events was 8.5% on FF/VI100/25mcg, 7.7% on placebo. The incidence of pneumonia was 5.7% on FF/VI 100/25mcg and 5.2% on placebo and the incidence of serious pneumonia was 3.4% on FF/VI 100/25mcg and 3.1% on placebo.

The results will be the subject of future publications and presentations, including at the European Respiratory Society (ERS) International Congress in September.

Eric Dube, SVP and Head, Global Respiratory Franchise, GSK said: "SUMMIT is an important study as this is the first time that survival has been studied in this under-researched co-morbid patient population. While we didn't

achieve statistical significance on the primary endpoint, we believe the full data set will be beneficial and informative to the respiratory and cardiovascular scientific community. Relvar/Breo 100/25mcg continues to play an important role in the treatment of appropriate patients with COPD and as leaders in respiratory, GSK remains committed to tackling the major challenges that physicians and patients face in the treatment of respiratory disease."

Lead investigator, Jørgen Vestbo,Professor of Respiratory Medicine at the Centre for Respiratory Medicine and Allergy, University Hospital South Manchester NHS Foundation Trust and the University of Manchester, said: "We have long known that CVD often coexists with COPD and that each disease is a leading cause of death globally. The SUMMIT study is the first prospective study to investigate the interaction between these two diseases and set out to achieve the ambitious goal of demonstrating a reduction in death from any cause in patients with both COPD and CVD. While the study was unable to demonstrate a statistically significant improvement on this endpoint, it provides us with a wealth of data to help us as clinicians understand the interplay between these two conditions and insights on how to improve the management of these patients."

Michael W. Aguiar, President and Chief Executive Officer of Theravance, Inc., said: "While we were unable to demonstrate a statistically significant survival benefit in this population, the full data set from SUMMIT, the largest study with Relvar/Breo conducted to date, provides additional confidence in the safety and efficacy of Relvar/Breo 100/25mcg as a once-a-day treatment to improve lung function and reduce exacerbation risk in patients with COPD."

About the Study
The Study to Understand Mortality and MorbidITy (SUMMIT) in COPD is the first prospective study that aims to understand the effect of respiratory treatments in patients with COPD and a history or risk of CVD.

It is a placebo-controlled, double-blind, randomised, parallel group, multi-centre trial. COPD patients with moderate airflow limitation (>50 and <70% predicted FEV1) 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. All comparisons for the primary, secondary and other endpoints were performed at the two-sided 5% level of significance.

*In all arms of the study, patients were permitted to use study-supplied albuterol/salbutamol (short-acting beta-2 agonists, 'SABA'). If subjects experienced multiple moderate COPD exacerbations or a severe COPD exacerbation during the study, a long-acting muscarinic antagonist (LAMA) or PDE IV inhibitor was permitted. Oral corticosteroids and antibiotics were also permitted for the short-term treatment of COPD exacerbations during the study. Patients were able to continue taking cardiovascular medications throughout the duration of the study. Use of any inhaled corticosteroid (ICS) or long-acting beta-2 agonist (LABA) while on double-blind treatment was not permitted.

The primary endpoint was time to death from any cause, to evaluate the effect of FF/VI 100/25mcg on survival compared with placebo. The secondary endpoints were:
· the effect of FF/VI 100/25mcg compared with placebo on the rate of decline in lung function, as measured by FEV1. This is the amount of air you can forcefully blow out of your lungs in one second and is used as a measure of disease progression that is associated with mortality.
· the effect of FF/VI 100/25mcg compared with placebo on a CV composite endpoint comprised of on-treatment CV death, myocardial infarction, stroke, unstable angina and transient ischemic attack (TIA).

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.1 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.2,3 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.3,4

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 FEV1<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

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 beta2-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 beta2-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.

For asthma, the most common adverse reactions in a 12-week trial (incidence ≥2% and more common than placebo) reported with Breo Ellipta 100/25 (and placebo) were nasopharyngitis 10% (7%), headache 5% (4%), oropharyngeal pain 2% (1%), oral candidiasis 2% (0%), and dysphonia 2% (0%). In a separate 12-week trial the most common adverse reactions (≥2% incidence) reported with Breo Ellipta 100/25 or 200/25 were headache, nasopharyngitis, influenza, upper respiratory tract infection, oropharyngeal pain, sinusitis, bronchitis, and cough. In addition to adverse reactions reported in the 12 week studies, adverse reactions (≥2% incidence) reported with Breo Ellipta 200/25 in a 24-week trial included viral respiratory tract infection, pharyngitis, pyrexia, and arthralgia, and with Breo Ellipta 100/25 or 200/25 in a 12-month trial included pyrexia, back pain, extrasystoles, upper abdominal pain, respiratory tract infection, allergic rhinitis, pharyngitis, rhinitis, arthralgia, supraventricular extrasystoles, ventricular extrasystoles, acute sinusitis, and pneumonia.

RELVAR®, BREO® and ELLIPTA® are trade marks of the GlaxoSmithKline group of companies.

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.

Theravance, Inc. -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. Theravance'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 Theravance and GSK. Under the agreement with GSK, Theravance is eligible to receive associated royalty revenues from RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and, if approved and commercialized, VI monotherapy, as well. In addition, Theravance retains a 15% economic interest in future payments made by GSK for earlier-stage programs under the agreements with GSK. For more information, please visit Theravance's website at www.thrxinc.com.


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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 2014.

Theravance 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. Theravance 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: the commercial and regulatory plans for BREO ELLIPTA, 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 cash dividends or future share repurchases), 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 product candidates through development and commercialization, the timing of seeking regulatory approval of product candidates, and projections of revenue, expenses and other financial items. These statements are based on the current estimates and assumptions of the management of Theravance 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 Theravance 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: the disruption of operations during the transition period following the spin-off, including the diversion of managements' and employees' attention, disruption of relationships with collaborators and increased employee turnover, 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 Theravance are described under the headings

"Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Theravance's Annual Report on Form 10-K for the year ended December 31, 2014 and Theravance's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, 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 Theravance's other filings with the SEC, other unknown or unpredictable factors also could affect Theravance's 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. Theravance assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law. (THRX-G)

Registered in England & Wales:
No. 3888792

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References

1. World Health Organization. The Top 10 Causes of Death Factsheet 310, May 2014. Available at: http://www.who.int/mediacentre/factsheets/fs310/en/. Last accessed August 2015.

2. Jones PW et al. Eur Respir J. 2013;42(Suppl 57):5036

3. GSK Data on file HZC115058

4. Johnston AK et al. Thorax 2008;32(4):962-9

SIGNATURES

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, thereunto duly authorised.

GlaxoSmithKline plc
(Registrant)

Date: September 08, 2015

By: VICTORIA WHYTE
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Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc