GLAXOSMITHKLINE PLC
Form 6-K
September 06, 2016

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 05 September 2016

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

--

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

Issued: Sunday 4th September 2016

GSK announce positive results from the COPD Salford Lung Study published in the NEJM and presented at European Respiratory Congress

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced that the results from the pioneering Salford Lung Study (SLS) have been published in the New England Journal of Medicine (NEJM). This unique study, which reported headline results in May 2016, was designed to evaluate the effectiveness and safety of Relvar® Ellipta® in patients with chronic obstructive pulmonary disease (COPD), compared with their 'usual care' administered in an everyday clinical practice setting. Data from the study are being presented at the European Respiratory Society (ERS) International Congress on Sunday 4th September in London, (abstract number OA249).

For the primary endpoint in patients, who had exacerbated in the year before the study, treated with Relvar Ellipta 100/25mcg (fluticasone furoate 'FF'/vilanterol 'VI' or 'FF/VI') there was a statistically significant reduction of 8.4% (p=0.025; 95% CI 1.1 to 15.2) in the rate of moderate or severe exacerbations compared with patients receiving 'usual care'. The majority of these patients in the study on usual care were taking an inhaled corticosteroid (ICS) containing regimen (88%). A similar reduction in exacerbations with FF/VI was seen in those patients on an ICS/long-acting beta2-agonist (LABA) at baseline (8.0%; 95% CI 0.11 to 15.4, p=0.047).

For the intent to treat (ITT) population there were no differences observed between FF/VI and usual care on secondary outcomes measured including the time to first moderate or severe exacerbation and rate of severe exacerbations, the rate of secondary care healthcare contacts and COPD related primary care contacts. There were more primary care contacts overall on FF/VI (12.3% increase, 95% CI 5.4 to19.6). The COPD Assessment Test (CAT), which measures the impact of disease on health status, demonstrated 45% of patients receiving FF/VI improved their CAT score by 2 or more, a clinically relevant improvement, compared to 36% in the usual care group (odds ratio 1.51, 95% CI, 1.28 to 1.77).

The incidence of serious adverse events (SAE) was similar between the groups (29% FF/VI, 27% usual care). For pneumonia, an SAE of special interest, FF/VI demonstrated non-inferiority (7% FF/VI vs 6% usual care). This endpoint was a post-authorisation measure requested by the European Medicines Agency (EMA).

Neil Barnes, Global Medical Head, Respiratory Franchise at GSK said: "In the SLS study we included a broad spectrum of patients who had minimal interventions to see if this would allow us to observe a difference between treatments. The results from SLS provide robust evidence that will enable the healthcare community to begin to understand how the choice of COPD treatment can significantly influence patient outcomes. We are continuing to analyse the data from the study as we know there is so much more we will learn and we look forward to sharing our findings in future publications. I want to thank all of the patients who participated and the partners who collaborated with GSK to make this unique study possible."

Michael W. Aguiar, President and Chief Executive Officer of Innoviva said: "The data being presented at ERS and published in NEJM confirm the effectiveness of Relvar Ellipta compared with not only usual care, but also with those patients who were taking a different medicine in the same ICS/LABA class. These are important data to share with physicians, from a unique study carried out in conditions closely reflecting everyday clinical practice."

The study was made possible through collaboration between GSK, North West e-Health (NWEH), The University of Manchester, Salford Royal NHS Foundation Trust, University Hospital of South Manchester (UHSM), NHS Salford and GPs and community pharmacists in Salford, Trafford and South Manchester.

A second Salford Lung Study is currently being conducted in patients with asthma, with results expected in 2017.

Study Design
The Salford Lung Study is a Phase IIIb multi-centre, open label randomised controlled trial (RCT). The objective of the SLS COPD study was to compare the effectiveness and safety profile of FF/VI 100/25mcg with existing COPD usual care. All suitable patients with COPD at 80 primary care sites in and around Salford and South Manchester were identified from practice databases, and invited to participate in the study by their own GP.

In total, 2802 patients with COPD were randomised 1:1 to receive FF/VI 100/25mcg, with or without a long-acting muscarinic antagonists (LAMA), or to continue to receive usual care. FF/VI was administered once daily via the Ellipta inhaler. Patients who were taking a LAMA in addition to ICS/LABA therapy (triple therapy) who were randomised to the FF/VI group were able to continue to use LAMA therapy in addition to FF/VI. Usual care was taken as advised by the prescribing clinician, and could include single or dual long-acting bronchodilator therapy, inhaled corticosteroid either alone or in combination with a long acting bronchodilator or triple therapy of a LAMA, a LABA and an inhaled corticosteroid.

The Salford Lung Study had minimal exclusion criteria and involved a broad demographic of patients. Patients were followed for a period of 12 months in a normal clinical practice setting using a single electronic medical record (EMR), linking primary care (patients seen by their general practitioner), secondary care (patients seen in a hospital setting) and pharmacy data. Throughout the duration of the study physicians were allowed to modify or switch treatment at any point in the study, as would happen in normal clinical practice, the only exception being a switch from usual care to FF/VI.

The study team was able to monitor all hospital admissions, outpatient and emergency department visits, as well as data from primary care (including all healthcare contacts, out-of-hours activity and prescriptions of antibiotics or oral steroids) via the electronic health-records.

The primary effectiveness endpoint is the mean annual rate of moderate or severe exacerbations, where a moderate exacerbation is defined as the subject receiving an exacerbation-related prescription (given to treat an acute worsening of COPD symptoms) of oral corticosteroid and/or antibiotic with or without NHS contact, not requiring hospitalisation. A severe exacerbation is defined as an exacerbation-related hospitalisation - a direct result of an acute worsening of symptoms of COPD or a prolonged hospitalization as a result of a COPD exacerbation.

What is COPD?
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.

People with COPD can experience a sudden worsening in symptoms, known as an exacerbation. Symptoms of an exacerbation can include an increase in breathlessness, coughing and mucus production, as well as fever. In these cases, the patient may need to change their medication or even, in some cases, be admitted to hospital. Exacerbations are common; one in three patients with severe COPD and almost half of patients with very severe COPD had frequent exacerbations (two or more in the first year following diagnosis). Every exacerbation can cause permanent lung damage and repeated exacerbations can accelerate the progression of the disease. People with frequent exacerbations have a poorer quality of life and may have an increased risk of death.

The study is listed on www.clinicaltrials.gov.

Relvar® Ellipta® is known as Breo® Ellipta® in the United States.

About FF/VI 100/25

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.

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.

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.

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.

GSK enquiries:
UK Media enquiries: David Mawdsley +44 (0) 20 8047 5502 (London)

	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
	Catherine Hartley	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Sarah Alspach	+1 202 715 1048	(Washington, DC)
	Sarah Spencer	+1 215 751 3335	(Philadelphia)
	Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
	Jenni Ligday	+1 202 715 1049	(Washington, DC)
	Karen Hagens	+1 919 483 2863	(North Carolina)
	Gwynne Oosterbaan	+1 215 751 7468	(Philadelphia)
Analyst/Investor enquiries:	Ziba Shamsi	+44 (0) 20 8047 5543	(London)
	Tom Curry	+ 1 215 751 5419	(Philadelphia)
	Gary Davies	+44 (0) 20 8047 5503	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)

Innoviva Inc. enquiries:

Investor Relations	Eric d'Esparbes	+1 650 808 4100	(Brisbane, Calif.)

investor.relations@inva.com

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: the future use or importance of the SLS trial results, 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 June 30, 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)

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

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 05, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc