GLAXOSMITHKLINE PLC
Form 6-K
February 23, 2017

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 23 February 2017

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

GlaxoSmithKline plc (the 'Company')

Issued: Thursday 23 February 2017 London UK - LSE Announcement

Positive results for Relvar® Ellipta® lung function study in patients with well-controlled asthma

GlaxoSmithKline plc (LSE/NYSE:GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced positive headline results from a non-inferiority lung function study, which demonstrated that patients with well-controlled asthma were able to switch to the once-daily Relvar® Ellipta® (fluticasone furoate/vilanterol, FF/VI) 100/25, an inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) combination, from the twice-daily Seretide® Accuhaler® (fluticasone propionate /salmeterol, FP/SAL) 250/50, without compromising their lung function.

Patients randomised to FF/VI taken once-daily maintained lung function comparable with those randomised to the twice-daily FP/SAL [difference +19mL (95% CI: -11mL, +49mL], meeting the study's primary endpoint, based on the lower bound (-11ml) of the 95% confidence interval falling above the non-inferiority margin of -100mL.

A third treatment arm with fluticasone propionate (FP), ICS monotherapy, was included to detect a lung function difference between treatments. Results demonstrated statistically significant differences in favour of the ICS/LABA combinations to FP ($p<0.001$).

The incidences of on-treatment serious adverse events (SAEs) and adverse events (AEs) of special interest were consistent with the known safety profile of FF/VI, established in asthma patients from other studies.

Eric Dube, SVP and Global Head of Respiratory Franchise, GSK said: At GSK we are constantly searching for ways in which we can help patients better manage their asthma. In this positive study we have demonstrated non-inferiority for once-daily Relvar versus twice-daily Seretide on lung function. This gives us confidence that for patients who struggle taking a twice-daily treatment regimen, there may be a once-daily treatment option available, providing greater physician choice to help patients."

Mike Aguiar, CEO of Innoviva, Inc., added: "We believe the results of this study are important for patients and physicians. They provide additional evidence that patients with persistent asthma, who are currently treated with a twice-daily ICS/LABA, in this case Seretide, can experience a similar level of benefit in lung function when treated with Relvar Ellipta, which only needs to be taken once a day."

The study design was agreed with European regulatory authorities. GSK now intends to submit this data to the European Medicines Agency (EMA).

Results from the study will be shared in future publications and presentations.

Study Design
Following a 4-week open-label treatment period with FP/SAL 250/50 twice-daily, patients with well controlled asthma were randomised to receive either FF/VI 100/25 once-daily, FP/SAL 250/50 twice-daily or FP 250 twice-daily in a double-blind, double-dummy manner for 24 weeks at multiple centres in 12 countries.

The primary objective of the study was to demonstrate non-inferiority of Relvar Ellipta 100/25 once-daily with Seretide Accuhaler 250/50 twice-daily in adult and adolescent subjects 12 years of age and older with persistent bronchial asthma, well controlled on twice-daily ICS/LABA. The endpoint for the study was the change from baseline in clinic visit evening FEV1 (pre-brochodilator and pre-dose) at the end of the 24-week treatment period.

To demonstrate the non inferiority of FF/VI vs FP/SAL the lower limit of the 95% confidence interval for the mean difference in change from baseline for evening FEV1 needed to be greater than the pre defined margin of -100mL.

This was to rule out the possibility that FF/VI was more than -100mL inferior to FP/SAL.

About asthma
Asthma is a chronic lung disease that inflames and narrows the airways. Asthma affects 358 million people worldwide. Despite medical advances, more than half of patients continue to experience poor control and significant symptoms impacting their daily life.

The causes of asthma are not completely understood but likely involve an interaction between a person's genetic make-up and the environment. Key risk factors are inhaled substances that provoke allergic reactions or irritate the airways.

About Relvar Ellipta (fluticasone furoate + vilanterol)
Relvar Ellipta is a once-daily dual combination treatment comprising fluticasone furoate, an inhaled corticosteroid and vilanterol, a long-acting beta2-agonist, in a single inhaler, the Ellipta®.

Relvar Ellipta is indicated in Europe in the regular treatment of patients aged 12 and over with asthma, where use of a combination product (long-acting ß2-agonist, LABA, and inhaled corticosteroid, ICS) is appropriate: Patients not adequately controlled on both ICS and 'as-needed' short-acting ß2-agonist (SABA).
Full EU prescribing information is available at: EU Prescribing Information for Relvar Ellipta.

Important safety information for Relvar Ellipta in Europe
FF/VI is contraindicated in patients with hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients.

FF/VI should not be used to treat acute asthma symptoms or an acute exacerbation in COPD, for which a short-acting bronchodilator is required. Increasing use of short-acting bronchodilators to relieve symptoms indicates deterioration of control and patients should be reviewed by a physician.

Patients should not stop therapy with FF/VI in asthma or COPD, without physician supervision since symptoms may recur after discontinuation.

Asthma-related adverse events and exacerbations may occur during treatment with FF/VI. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of treatment with FF/VI.

Paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with a short-acting inhaled bronchodilator. FF/VI should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary.

Cardiovascular effects, such as cardiac arrhythmias e.g. supraventricular tachycardia and extrasystoles may be seen with sympathomimetic medicinal products including FF/VI. Therefore fluticasone furoate/vilanterol should be used with caution in patients with severe cardiovascular disease.

For patients with moderate to severe hepatic impairment, the 92/22 mcg dose should be used and patients should be monitored for systemic corticosteroid-related adverse reactions. FF/VI 184/22 mcg is not indicated for patients with COPD. There is no additional benefit of the 184/22 mcg dose compared to the 92/22 mcg dose and there is a potential increased risk of pneumonia and systemic corticosteroid-related adverse reactions.

An increase in the incidence of pneumonia has been observed in subjects with COPD receiving FF/VI. There was also an increased incidence of pneumonias resulting in hospitalisation. In some instances these pneumonia events were fatal.

The incidence of pneumonia in patients with asthma was common at the higher dose. In a previous study of FF/VI in asthma the incidence of pneumonia in patients with asthma taking FF/VI 184/22 mcg was numerically higher compared with those receiving FF/VI 92/22 mcg or placebo.

Hyperglycaemia: There have been reports of increases in blood glucose levels in diabetic patients and this should be considered when prescribing to patients with a history of diabetes mellitus.

Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, growth retardation in children and adolescents, cataract and glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

FF/VI should be administered with caution in patients with pulmonary tuberculosis or in patients with chronic or untreated infections. Data from large asthma and COPD clinical trials were used to determine the frequency of adverse reactions associated with FF/VI.

Very common adverse reactions (occurring in >1/10 patients) with FF/VI were headache and nasopharyngitis. Common adverse reactions (occurring in >1/100 to <1/10 patients) were pneumonia, upper respiratory tract infection, bronchitis, influenza, candidiasis of mouth and throat, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, fractures, and pyrexia and muscle spasms..Extrasystoles were observed as an uncommon adverse reaction (occurring in >1/1,000 to <1/100 patients). Rare adverse reactions (occurring in >1/10,000 to < 1/1,000) were hypersensitivity reactions (including anaphylaxis, angioedema, rash and urticaria), anxiety, tremor, palpitations, tachycardia and paradoxical bronchospasm. With the exception of pneumonia and fractures, the safety profile was similar in patients with asthma and COPD. During clinical studies, pneumonia and fractures were more frequently observed in patients with COPD.

Relvar Ellipta is known as Breo Ellipta in the United States. Breo Ellipta is licensed in the US for:

The once-daily treatment of asthma in patients aged 18 years and older.

Long-acting beta2-adrenergic agonists (LABA), such as vilanterol, one of the active ingredients in Breo Ellipta, increase the risk of asthma-related death. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe Breo Ellipta for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid, or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and a LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue Breo Ellipta) if possible without loss of asthma control and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use BREO ELLIPTA for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids.

Breo Ellipta 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 for Breo Ellipta.

About Seretide Accuhaler (fluticasone propionate + salmeterol)

Seretide Accuhaler is a twice-daily dual combination treatment comprising fluticasone propionate /salmeterol, in the Accuhaler inhaler.

Seretide Accuhaler is indicated in Europe in the regular treatment of patients aged 4 and over with asthma, where use of a combination product (long-acting ß2-agonist, LABA, and inhaled corticosteroid, ICS) is appropriate: Patients not adequately controlled on both ICS and 'as-needed' short-acting ß2-agonist (SABA); Patients already adequately controlled on both ICS and LABA.
For the UK Summary of Product Characteristics (SmPC), please visit:
https://www.medicines.org.uk/emc/medicine/2317/SPC/Seretide+100,+250,+500+Accuhaler
Important safety information for Seretide Accuhaler
Uses: Asthma: Regular treatment of asthma, where a long-acting b2 agonist and inhaled corticosteroid is appropriate, i.e. patients uncontrolled on inhaled corticosteroids and 'as needed' short-acting inhaled bronchodilator or patients controlled on inhaled corticosteroid and long-acting b2 agonist. Lowest strength Seretide (salmeterol 25mcg/fluticasone propionate 50 mcg and salmeterol 50mcg/fluticasone propionate 100 mcg) not appropriate in severe asthma. COPD: Symptomatic treatment of patients with COPD with a FEV1 <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy.

Dosage and administration: Inhalation only. Asthma: Adults and adolescents 12 years and over: Seretide Accuhaler - one inhalation b.d. of: Seretide 100 (salmeterol 50 mcg/fluticasone propionate 100 mcg) or Seretide 250 (salmeterol 50 mcg/fluticasone propionate 250 mcg) or Seretide 500 (salmeterol 50 mcg/fluticasone propionate 500 mcg), Seretide Evohaler - two puffs b.d. of: Seretide 50 (salmeterol 25 mcg/fluticasone propionate 50 mcg) or Seretide 125 (salmeterol 25 mcg/fluticasone propionate 125mcg) or Seretide 250 (salmeterol 25 mcg/fluticasone propionate 250 mcg). Children 4-11 years: Seretide 50 Evohaler (salmeterol 25 mcg/fluticasone propionate 50 mcg): two puffs b.d. Spacer recommended for co-ordination. Seretide 100 Accuhaler (salmeterol 50 mcg/fluticasone propionate 100 mcg) one inhalation b.d. Regularly review patients and reduce dose to lowest that maintains effective symptom control. Where the control of symptoms is maintained with the lowest strength of the combination, patients may be prescribed an inhaled corticosteroid alone, or if a long-acting b2 agonist is required, Seretide may be given once daily. If rapid control of asthma in adults or adolescents with moderate persistent asthma (defined as patients with daily symptoms, daily rescue use and moderate to severe airflow limitation) is essential, an initial dose of two inhalations b.d of Seretide 50 Evohaler (salmeterol 25 mcg/fluticasone propionate 50 mcg) or one inhalation b.d of Seretide 100 Accuhaler (salmeterol 50 mcg/fluticasone propionate 100 mcg) may be considered on a short-term basis. Once control of asthma is attained treatment should be regularly reviewed and stepped down. Doubling the dose of all strengths of Seretide may be considered when adult patients require additional short-term (up to 14 days) inhaled corticosteroid therapy but this causes a small increase in b-agonist-related adverse events. COPD: one inhalation b.d. of Seretide 500 Accuhaler (salmeterol 50mcg/fluticasone propionate 500 mcg).

Contraindications: Hypersensitivity to the active ingredients or to any of the excipients.

Precautions: Pulmonary tuberculosis, fungal, viral or other infections of the airway, severe cardiovascular disorders, heart rhythm abnormalities, diabetes mellitus, hypokalaemia and thyrotoxicosis. Increased reporting of pneumonia and bronchitis in patients with COPD receiving Seretide compared with placebo. If a patient with severe COPD has experienced pneumonia, treatment with Seretide should be re-evaluated. Paradoxical bronchospasm post dose. Severe unstable asthma: Warn patients to seek medical advice if short-acting inhaled bronchodilator use increases. Consider increased inhaled/additional corticosteroid therapy. Acute symptoms: Not for acute symptoms. Use short-acting inhaled bronchodilator. Systemic effects: Systemic effects of inhaled corticosteroids may occur, particularly at high doses for prolonged periods, but much less likely than with oral corticosteroids. May include Cushing's syndrome, cushingoid features, adrenal suppression, adrenal crisis, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma and, more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). Monitor height of children on prolonged inhaled corticosteroid therapy. Tremor, palpitations and headache, have been reported

with b2 agonist treatment. In asthma, therapy should be down titrated under physician supervision to lowest effective dose and treatment should not be abruptly stopped due to risk of exacerbation. Serious asthma-related adverse events and exacerbations may occur during treatment with Seretide. Patients should not be initiated on Seretide during an exacerbation, or if they have significantly worsening or acutely deteriorating asthma. Data from a large asthma trial suggested patients of black African or Afro-Caribbean ancestry were at increased risk of serious respiratory-related events or deaths when using salmeterol. All patients should continue treatment but seek medical advice if asthma symptoms remain uncontrolled or worsen when initiated on Seretide or using Seretide. In COPD cessation of therapy may also be associated with decompensation and should be supervised by a physician. Transfer from oral steroids: Special care needed. Consider appropriate steroid therapy in stressful situations.

Drug interactions: Avoid beta-blockers. Avoid concomitant administration of ketoconazole or other potent (e.g. itraconazole, telithromycin, ritonavir) and moderate (erythromycin) CYP3A4 inhibitors unless benefits outweigh potential risk. b2 adrenergic blockers may weaken or antagonise the effect of salmeterol. Potentially serious hypokalaemia may result from 2 agonist therapy. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics.

Pregnancy and lactation: Experience limited. Balance risks against benefits.

Side effects: Very Common: headache, nasopharyngitis. Common: candidiasis of the mouth and throat, hoarseness/dysphonia, throat irritation, pneumonia, bronchitis, hypokalaemia, sinusitis, contusions, traumatic fractures, arthralgia, myalgia, muscle cramps. Uncommon: respiratory symptoms (dyspnoea), anxiety, tremor, palpitations, tachycardia, angina pectoris, atrial fibrillation, cutaneous hypersensitivity reactions, hyperglycaemia, sleep disorders, cataract. Rare: angioedema, respiratory symptoms (bronchospasm), anaphylactic reactions including anaphylactic shock, Cushings syndrome, cushingoid features, adrenal suppression, growth retardation in children and adolescents, decreased bone mineral density, oesophageal candidiasis, behavioural changes including psychomotor hyperactivity and irritability (predominately in children), glaucoma, cardiac arrhythmias and paradoxical bronchospasm. Not known: depression or aggression (particularly in children). Paradoxical bronchospasm: substitute alternative therapy.

Seretide Accuhaler is known as ADVAIR DISKUS in the United States. ADVAIR DISKUS is licensed in the US for:

The treatment of asthma in patients aged 4 years and older.

Long-acting beta2-adrenergic agonists (LABA), such as salmeterol, one of the active ingredients in ADVAIR DISKUS, increase the risk of asthma-related death. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe ADVAIR DISKUS for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid, or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and a LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue ADVAIR DISKUS) if possible without loss of asthma control and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use ADVAIR DISKUS for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids.

ADVAIR DISKUS 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 for Advair Diskus.

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.

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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®. In addition, Innoviva retains a 15 percent economic interest in future payments made by GSK for earlier-stage programs partnered with Theravance Biopharma, Inc., including the closed triple combination therapy for COPD. For more information, please visit Innoviva's website at www.inva.com.

GSK enquiries:

UK Media enquiries:	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
	Anna Gibbins	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Sarah Alspach	+1 202 715 1048	(Washington, DC)
	Sarah Spencer	+1 215 751 3335	(Philadelphia)
	Karen Hagens	+1 919 483 2863	(North Carolina)
Analyst/Investor enquiries:	Sarah Elton-Farr	+44 (0) 208 047 5194	(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) 238-9605 investor.relations@inva.com	(Brisbane, Calif.)

GSK cautionary statement regarding forward-looking statementsGSK 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, including the development, regulatory and commercial plans for closed triple combination therapy and the potential benefits and mechanisms of action of closed triple combination therapy. 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. 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 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, which are on file with the U.S. Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Innoviva's Annual Report on Form 10-K for the year ended December 31, 2016, to be filed with the SEC in the first quarter of 2017.. 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. 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. The information in this press release is provided only as of the date hereof, and 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: February 23, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc