GLAXOSMITHKLINE PLC
Form 6-K
October 27, 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 October 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

--

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: Tuesday 27 October 2015, London UK - LSE Announcement

GSK's Advair ® Diskus® achieves primary endpoint in LABA safety study of patients with asthma

GlaxoSmithKline plc (GSK) today announced results from the 'LABA' (long acting beta2-agonist) safety study, AUSTRI (SAS115359). The study compared Advair® Diskus®, a combination of the LABA, salmeterol, and the inhaled corticosteroid (ICS), fluticasone propionate (FP), to FP monotherapy and showed that Advair (FSC) had a safety profile comparable to FP when used to treat adolescent and adult patients with asthma, assessed by the composite endpoint of serious asthma-related events (deaths, intubations or hospitalisations).

Results from the 26-week AUSTRI study, which randomised 11,751 patients across 33 countries into the study, showed FSC twice-daily (100/50mcg, 250/50mcg or 500/50mcg) demonstrated non-inferiority compared to corresponding doses of FP twice-daily (100mcg, 250mcg or 500mcg), on the risk of serious asthma-related events, Hazard Ratio (HR) 1.029, (95% CI 0.638, 1.662) p=0.003. No asthma-related deaths were seen in either arm of the study. There were a total of 67 patients with serious asthma-related events across the study with 34 patients with events on FSC treatment and 33 patients with events on FP treatment. There were two asthma-related intubations in the trial, both in the FP arm; the remaining events were asthma-related hospitalisations.

AUSTRI was undertaken as a post-marketing requirement of GSK for the US Food and Drug Administration (FDA). Three other manufacturers of LABA-containing products, which are also indicated for the treatment of asthma, undertook identical studies designed to evaluate whether the addition of a LABA to an ICS increased the risk of an event in the composite endpoint of serious asthma-related events (deaths, intubations or hospitalisations) in adolescents and adults. AUSTRI is the first of the large-scale safety studies to report results. These findings will be shared with the FDA to discuss next steps.

In addition to the AUSTRI study, GSK is also conducting a second LABA safety study, VESTRI, in children aged 4 - 11 years of age. This study will complete last patient last visit this week and is on track to report at the end of Q1 2016.

Study Design

AUSTRI Study (SAS115359)
A global, multicentre, randomised stratified, double-blind, parallel-group active comparator, 26 week study in adolescents (12 - 17 years of age) and adults (18 years of age and older) whose asthma warrants treatment with controller asthma therapy. Patients were required to have a history of asthma for at least one year prior to randomisation and experienced a severe asthma exacerbation requiring treatment with oral corticosteroids (or their equivalent) or an asthma-related hospitalisation in the year prior to treatment, but not in the 30 days prior to randomisation.

Patients were randomised to either FSC or FP. The FP (ICS) treatment dose (100mcg, 250mcg or 500mcg) was determined by the previous use of controller medications and an assessment of the patient's asthma control. Upon entry into the study, patients took part in a screening period of up to two weeks, a randomisation visit (visit 2) followed by a treatment period of 26 weeks where patients attended 3 on-treatment clinic visits. Months where there was not a visit, patients were contacted by telephone. Serious adverse events were collected within six months after the first use of study drug or seven days after the last date of study drug treatment, whichever date was greater. Patients were permitted to use albuterol/salbutamol rescue medication throughout the study.

The primary analysis was to determine whether the addition of LABA to ICS therapy (FSC) is non-inferior to ICS therapy alone (FP) on risk of a composite of serious asthma events (asthma-related hospitalisation, intubation and death). To demonstrate non-inferiority, a predefined margin of 2 was required, meaning the upper limit of the 95%

confidence interval needed to be less than two to rule out a doubling in the risk of incidence on FSC compared with FP. All serious asthma related events were adjudicated by an independent committee.

The full results for this study will be posted on the GSK Clinical Study Register and presented at a future scientific meeting.

About Advair/Seretide
ADVAIR DISKUS is indicated 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.

https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Advair_Diskus/pdf/ADVA

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 ADVAIR DISKUS

WARNING: ASTHMA-RELATED DEATH
Long-acting beta2-adrenergic agonists (LABA), such as salmeterol, one of the active ingredients in ADVAIR DISKUS, increase the risk of asthma-related death. Data from a large placebo-controlled US trial that compared the safety of salmeterol with placebo added to usual asthma therapy showed an increase in asthma-related deaths in subjects receiving salmeterol (13 deaths out of 13,176 subjects treated for 28 weeks on salmeterol versus 3 deaths out of 13,179 subjects on placebo). Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. 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.

CONTRAINDICATIONS

- ADVAIR DISKUS is contraindicated for primary treatment of status asthmaticus or other acute episodes of asthma or chronic obstructive pulmonary disease (COPD) where intensive measures are required.

- ADVAIR DISKUS is contraindicated in patients with severe hypersensitivity to milk proteins.

WARNINGS AND PRECAUTIONS

- ADVAIR DISKUS should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of asthma or COPD.

- ADVAIR DISKUS should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. An inhaled, short-acting beta2-agonist, not ADVAIR DISKUS, should be used to relieve acute symptoms such as shortness of breath.

- ADVAIR DISKUS should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using ADVAIR DISKUS should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol, vilanterol) for any reason.

- Oropharyngeal candidiasis has occurred in patients treated with ADVAIR DISKUS. Advise patients to rinse the mouth with water without swallowing following inhalation to help reduce the risk of oropharyngeal candidiasis.

- 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. Use caution in patients with the above because of the potential for worsening of these infections.

- 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. Slowly taper the dose of systemic corticosteroids if transferring patients to ADVAIR DISKUS.

- Hypercorticism and adrenal suppression may occur with high doses of inhaled corticosteroids, including fluticasone propionate, or at the recommended dose in susceptible individuals. If such effects occur, discontinue ADVAIR DISKUS slowly.

- The use of strong cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, telithromycin) with ADVAIR DISKUS is

not recommended because increased systemic corticosteroid and increased cardiovascular adverse effects may occur.

- If paradoxical bronchospasm occurs, discontinue ADVAIR DISKUS immediately and institute alternative therapy.

- Salmeterol, a component of ADVAIR DISKUS, can produce a clinically significant cardiovascular effect in some patients as measured by pulse rate, blood pressure, and/or symptoms. If such effects occur, ADVAIR DISKUS may need to be discontinued. ADVAIR DISKUS should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

- Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, advanced age, poor nutrition, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care.

- Inhaled corticosteroids, as well as poorly controlled asthma, may cause a reduction in growth velocity, and the long-term effect on final adult height is unknown. Patients should be maintained on the lowest dose of inhaled corticosteroid that effectively controls their asthma. Monitor growth of pediatric patients.

- Glaucoma, increased intraocular pressure, and cataracts have been reported in patients with asthma and COPD following the long term administration of inhaled corticosteroids, including fluticasone propionate, a component of ADVAIR DISKUS. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

- Be alert to hypokalemia, hyperglycemia, and systemic eosinophilic conditions, such as Churg-Strauss syndrome.

- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

ADVERSE REACTIONS

- Most common adverse reactions (incidence ≥3%) in subjects with asthma taking ADVAIR DISKUS 100/50, ADVAIR DISKUS 250/50, and placebo, respectively, were upper respiratory tract infection (27%, 21%, 14%), pharyngitis (13%, 10%, 6%), upper respiratory inflammation (7%, 6%, 5%), sinusitis (4%, 5%, 4%), hoarseness/dysphonia (5%, 2%, <1%), oral candidiasis (1%, 4%, 0%), viral respiratory infections (4%, 4%, 3%), bronchitis (2%, 8%, 2%), cough (3%, 6%, 2%), headaches (12%, 13%, 7%), nausea and vomiting (4%, 6%, 1%), gastrointestinal discomfort and pain (4%, 1%, 1%), diarrhea (4%, 2%, 1%), viral gastrointestinal infections (3%, 0%, 2%), candidiasis unspecified site (3%, 0%, 1%), and musculoskeletal pain (4%, 2%, 3%). The types of adverse reactions and events reported were similar in subjects treated with ADVAIR DISKUS 500/50.

DRUG INTERACTIONS

- The use of strong cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, telithromycin) with ADVAIR DISKUS is not recommended because increased systemic corticosteroid and increased cardiovascular adverse effects may occur.

- ADVAIR DISKUS should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, because the action of salmeterol, a component of ADVAIR DISKUS, on the vascular system may be potentiated by these agents.

- Use beta-blockers with caution as they not only block the pulmonary effect of beta-agonists, such as salmeterol, a component of ADVAIR DISKUS, but may also produce severe bronchospasm in patients with asthma or COPD.

- Use ADVAIR DISKUS with caution in patients taking non-potassium-sparing diuretics (such as loop or thiazide diuretics), as electrocardiographic changes and/or hypokalemia associated with non-potassium-sparing diuretics may worsen with coadministration with beta-agonists, such as salmeterol.

USE IN SPECIFIC POPULATIONS

- Fluticasone propionate and salmeterol are predominantly cleared by hepatic metabolism. Impairment of liver function may lead to accumulation of fluticasone propionate and salmeterol in plasma. Therefore, patients with hepatic disease should be closely monitored.

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.

GSK enquiries:			
UK Media enquiries:	Simon Steel	+44 (0) 20 8047 5502	(London)
	Claire Brough	+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)
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)

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.

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: October 27, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc