GLAXOSMITHKLINE PLC
Form 6-K
December 02, 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 02 December 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

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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

Issued: Friday 2 December 2016, London UK

Relvar® Ellipta® 100/25 mcg gains approval in Japan for use in patients with COPD

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved Relvar® Ellipta® (fluticasone furoate / vilanterol 100/25 mcg) for the relief of various symptoms with chronic obstructive pulmonary disease (chronic bronchitis, pulmonary emphysema) (in the case where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist is required).

Relvar is a combination of the inhaled corticosteroid (ICS), fluticasone furoate 'FF', and the long-acting beta2 agonist (LABA), vilanterol 'VI'. The approved dose of FF/VI in chronic obstructive pulmonary disease (COPD) is 100/25 mcg administered once-daily using the Ellipta dry powder inhaler (DPI). Relvar Ellipta has been approved in Japan for the treatment of asthma since 2013 in two strengths - 100/25 mcg and 200/25 mcg.

Eric Dube, SVP & Head, GSK Global Respiratory Franchise, said, "COPD affects people in different ways, and a range of treatments are needed so that physicians can determine the right treatment for the right patient. GSK has over 45 years of experience in delivering medicines that meet the individual needs of patients with respiratory diseases. We are delighted with this approval of Relvar Ellipta, our third COPD treatment to gain marketing authorisation in Japan in under three years, and believe it will be an important new option for appropriate patients with COPD, as well as those with asthma."

"The approval of Relvar Ellipta for COPD will provide Japanese physicians with a new, important once-daily, inhaled treatment option for appropriate patients," said Mike Aguiar, CEO of Innoviva, Inc. "This represents yet another significant milestone in the respiratory partnership between Innoviva and GSK."

The MHLW assessment of FF/VI was based on data from the global clinical development programme, as well as results from a global phase III study (study 200820) which was conducted to provide efficacy and safety data for the combination, FF/VI, compared with its component, VI, specifically in Japanese patients with COPD.

About Relvar Ellipta
Relvar Ellipta (FF/VI) was approved for the treatment of bronchial asthma (in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist is required) in Japan in 2013.

Relvar Ellipta is also known as Breo Ellipta in some other markets, including the US.

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. COPD is thought to affect approximately 8.6% of the population aged over 40 in Japan.[i]

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.[ii]

Important Safety Information for Relvar Ellipta (FF/VI)
The following Important Safety Information (ISI) is based on a summary of the Japanese Drug Information for Relvar Ellipta. Please consult the full Drug Information for all the labeled safety information for Relvar Ellipta.

FF/VI is contraindicated in patients with hypersensitivity to fluticasone furoate, vilanterol, or any of the excipients and in patients with infections or deep mycosis against which there is no effective anti-bacterial agent (symptoms may be exacerbated due to steroid effects).
Relvar Ellipta is not indicated for acute treatment of COPD exacerbation. Because FF/VI is not intended for immediate relief of symptoms or COPD exacerbations that have occurred, the product should not be used to relieve acute symptoms. Another appropriate drug such as short-acting inhaled beta2 agonist (e.g. inhaled salbutamol sulphate) should be used for relief of acute symptoms or COPD exacerbation.
FF/VI should be administered with caution in patients with tuberculosis or infections, patients with severe cardiac disease, and patients with hepatic impairment.
Patients should be cautioned to visit a medical institution as soon as possible to seek medical treatment if they notice increasing use or insufficient effect of the short-acting inhaled beta2agonist because asthma or COPD management may be inadequate.
Patients should be instructed not to stop inhaling FF/VI on their own since symptoms may be exacerbated after discontinuation of the product.
As with other inhaled drugs, paradoxical bronchospasm may occur with an increase in wheezing after inhalation of FF/VI. In such a case, FF/VI should be discontinued immediately, and treatment with a short-acting inhaled bronchodilator should be given. The patient should be assessed and alternative therapy should be considered if necessary.
Asthma-related events and asthma exacerbations may occur during treatment with FF/VI. Patients should be instructed not to stop inhaling FF/VI on their own but to seek medical advice if asthma symptoms remain uncontrolled or are exacerbated after initiation of treatment with the product.
Systemic effects (including Cushing's syndrome, Cushingoid symptoms, adrenal suppression, growth retardation in children, decrease in bone mineral density, cataract, and glaucoma) may occur with inhaled steroids although these effects are less likely than with systemic steroids. Therefore, inhaled steroids should be used at the lowest dose to effectively control asthma for each patient. Particularly, patients who are treated at high doses for long periods should be monitored with regular examinations; in case systemic effects occur, appropriate measures should be taken while monitoring the patient's asthmatic symptoms.
It has been reported in a global clinical study and overseas clinical studies in patients with chronic obstructive pulmonary disease that the incidence of pneumonia showed a FF/VI dose-dependent increase. Caution should be exercised when FF/VI is administered to patients who are generally at potentially high risk for developing pneumonia.
Caution should be exercised when considering the coadministration of FF/VI with long-term ketoconazole and other known strong CYP3A4 inhibitors because increased systemic corticosteroid and cardiovascular adverse effects may occur. Caution should also be exercised when considering the coadministration of FF/VI with beta-blockers which may weaken the effect of FF/VI.
Adverse reactions (asthma): In three global phase III clinical studies, adverse reactions including laboratory abnormalities were reported in 100 (7.1%) of a total of 1,407 patients (including 61 Japanese patients) treated with FF/VI. The common adverse reactions were dysphonia and oral candidiasis reported in 19 (1.4%) and 12 (0.9%) patients, respectively. Of 61 Japanese patients, adverse reactions including laboratory abnormalities were reported in 7 patients (11.5%). The common adverse reactions were dysphonia and oral candidiasis reported in 3 (4.9%) and 2 (3.3%) patients, respectively (at the time of approval).
In a Japanese long-term administration study, adverse reactions including laboratory abnormalities were reported in 40 (26.1%) of a total of 153 patients treated with FF/VI. The common adverse reactions were oral candidiasis and dysphonia reported in 16 (10.5%) and 10 (6.5%) patients, respectively (at the time of approval).
Adverse reactions (COPD): In three global phase III clinical studies and two overseas phase III clinical studies, adverse reactions including laboratory abnormalities were reported in 196 (9.7%) of a total of 2022 patients treated with FF/VI. The most frequent adverse reactions were oral candidiasis reported in 77 (3.8%), oropharyngeal candidiasis reported in 22 (1.1%), pneumonia reported in 8 (0.4%), and dysphonia reported in 8 (0.4%) (at the time of

approval).
In a Japanese long-term administration study, adverse reactions including laboratory abnormalities were reported in 12 (20.0%) of a total of 60 patients treated with Relvar Ellipta. The most frequent adverse reactions were dysphonia and decreased urine free-cortisol reported in 6 (10.0%) and 2 (3.3%) patients, respectively (at the time of approval).
An anaphylactic reaction may occur (incidence unknown). Patients treated with Relvar Ellipta should be monitored closely, and if an abnormality is observed, the treatment should be discontinued and appropriate measures should be taken.
Since pneumonia may be developed (incidence 0.5%), patients should be observed carefully, and in case abnormality is detected, an appropriate treatment should be given.
Japanese Drug Information will be available soon at http://glaxosmithkline.co.jp/healthcare/. Prior to the label being posted online, a copy of the label may be requested from one of the GSK Media or Investor Relations contacts listed in the "GlaxoSmithKline Inquiries" section at the end of this document.
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., including the closed triple combination therapy for COPD. For more information, please visit Innoviva's website at www.inva.com.

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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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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. 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 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. 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)

[i] Fukuchi Y. 2004. COPD in Japan: the Nippon COPD Epidemiology study. Respirology. 2004 Nov;9(4):458-65.
[ii] National Heart Lung and Blood Institute. Who is at risk for COPD? Accessed March 2014. Available at: https://www.nhlbi.nih.gov/health/health-topics/topics/copd/atrisk.html

Registered in England & Wales:
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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: December 02,2016

By: VICTORIA WHYTE

Victoria Whyte

Authorised Signatory for and on

behalf of GlaxoSmithKline plc