GLAXOSMITHKLINE PLC
Form 6-K
November 18, 2013

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 November 2013

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: Monday 18 November 2013, London UK and South San Francisco, CA- LSE announcement

RELVAR®ELLIPTA®receives European marketing authorisation for the treatment of asthma and COPD

GlaxoSmithKline plc (LSE/NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) announced today that the European Commission has granted marketing authorisation for RELVAR® ELLIPTA®, which is now licensed across 31 European countries for the following uses:

Asthma: the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short- acting beta2-agonists

COPD: 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.

Relvar is a combination of the inhaled corticosteroid (ICS), fluticasone furoate "FF", and the long-acting beta2-agonist (LABA), vilanterol "VI" (FF/VI). Two strengths of FF/VI have been licensed for the treatment of asthma (92/22 mcg and 184/22 mcg) and one strength has been licensed for the treatment of COPD (92/22 mcg). Both strengths will be administered once-daily using Ellipta, a new dry powder inhaler (DPI).

Darrell Baker, SVP & Head, GSK Global Respiratory Franchise, said, "For many years GSK has been focused on developing a portfolio of new treatments for patients across the world with asthma and COPD. We are delighted that Relvar Ellipta is now licensed, which means that healthcare professionals across Europe will have the option to prescribe an ICS/LABA that offers 24-hour efficacy from a once-daily dose, delivered in our new Ellipta inhaler."

"This is yet another important achievement and is testament to our successful partnership with GSK in respiratory disease," said Rick E Winningham, Chief Executive Officer of Theravance. "We are delighted that another significant regulatory body has granted marketing authorisation for Relvar Ellipta for the treatment of asthma and COPD and look forward to seeing the benefits of this effective once-daily treatment option in these patient populations."

Under the terms of the 2002 LABA collaboration agreement, Theravance is obligated to make a milestone payment to GSK of $15 million (USD) following marketing authorisation for Relvar Ellipta from the European Commission. A further $15 million (USD) payment to GSK will follow the launch of Relvar Ellipta in Europe.

As part of its assessment, the European Medicines Agency reviewed results of 10 clinical studies in 7,783 patients with COPD and 16 studies in 9,326 patients with asthma.

For the EU Summary of Product Characteristics for Relvar Ellipta, please visit http://ec.europa.eu/health/documents/community-register/index_en.htm. 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 "GSK Inquiries" section at the end of this document.

In Europe, the FF/VI strengths of 92/22 mcg and 184/22 mcg are specified as the delivered doses (emitted from the inhaler). The lower strength is equivalent to the 100/25 mcg pre-dispensed dose (contained inside the inhaler) and the higher strength is equivalent to the 200/25 mcg pre-dispensed dose.

About Asthma

Asthma is a chronic lung disease that inflames and narrows the airways, causing recurring periods of wheezing, chest tightness, shortness of breath and coughing which often occurs at night or early in the morning.1

Despite medical advances, more than half of patients continue to experience poor control and significant symptoms.2

The causes of asthma are not completely understood however key risk factors are inhaled substances that provoke allergic reactions or irritate the airways. These include smoke and allergens like dust mites and pets.1

About COPD

Chronic obstructive pulmonary disease (COPD) is a term referring to two lung diseases, chronic bronchitis and emphysema, that are characterised by obstruction to airflow that interferes with normal breathing.

Long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD.3 Cigarette smoke, breathing in second hand smoke, air pollution, chemical fumes or dust from the environment or workplace can all contribute to COPD.3 Most people who have COPD are at least 40 years old when symptoms begin. COPD-related exacerbations are typically defined as a worsening of symptoms that require medical intervention.3

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 micrograms 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 incidences these pneumonia events were fatal.

The incidence of pneumonia in patients with asthma was common at the higher dose. 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. Extrasystoles were observed as an uncommon adverse reaction (occurring in >1/1,000 to <1/100 patients). 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 licences and indications

FF/VI 100/25 mcg was licensed by the US Food and Drug Administration for use in patients with COPD in May 2013 under the trade name BREO®ELLIPTA™. In the US, Breo Ellipta is not indicated for the relief of acute bronchospasm or the treatment of asthma. Full US prescribing information, including BOXED WARNING and Medication Guide is available at us.gsk.com or US Prescribing Information Breo Ellipta.

FF/VI 100/25 mcg was also licensed for the treatment of COPD by Health Canada in July 2013 under the same trade name. In September 2013, FF/VI strengths of 100/25 mcg and 200/25 mcg were licensed by the Japanese Ministry of Health Labour and Welfare for the treatment of asthma under the trade name Relvar Ellipta.

B Kelly-Bisla
Corporate Secretariat
18 November 2013

RELVAR® , BREO® and ELLIPTA® are trademarks 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 - is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Theravance's key programmes include: RELVAR® ELLIPTA® or BREO®ELLIPTA™ (FF/VI), ANORO™ELLIPTA™ (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), GSK961081, each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist programme. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit Theravance's web site at www.theravance.com.

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GSK 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. Factors that may affect GSK' s operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

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. Examples of such statements include statements relating to the status and timing of clinical studies, data analysis and communication of results, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product candidates, statements concerning the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights and statements concerning expectations for product candidates through development and commercialization 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 its 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 delays or difficulties in commencing or completing clinical studies, the potential that results of clinical or non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, delays or failure to achieve regulatory approvals for product candidates, risks of relying on third-party manufacturers for the supply of our product and product candidates and risks of collaborating with third parties to develop and commercialize products. These and other risks are described in greater detail under the heading "Risk Factors" contained in Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 1, 2013 and the risks discussed in our other periodic filings with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance assumes no obligation to update its forward-looking statements.

(THRX-G)

References

1. Global Initiative for Asthma. Pocket Guide for asthma management and prevention. Updated 2012.
2. Demoly et al. Eur Respir Rev. 2012 Mar 1;21(123):66-74. doi: 10.1183/09059180.00008111.
3. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Pocket guide to COPD diagnosis, management and prevention

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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: November 18, 2013

By: SIMON BICKNELL

Simon Bicknell
Authorised Signatory for and on
behalf of GlaxoSmithKline plc