GLAXOSMITHKLINE PLC
Form 6-K
April 30, 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 April 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

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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: Thursday 30 April 2015, London, UK, and South San Francisco, CA, USA – LSE Announcement

FDA approves BREO® ELLIPTA® for the treatment of adults with asthma in the US

GlaxoSmithKline plc (LSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the US Food and Drug Administration (FDA) has approved BREO® ELLIPTA® (fluticasone furoate/vilanterol [FF/VI]) for the once-daily treatment of asthma in patients aged 18 years and older. Breo Ellipta is not indicated for the relief of acute bronchospasm.

Breo is a fixed-dose combination of the inhaled corticosteroid (ICS) fluticasone furoate (FF) and the long-acting beta2-agonist (LABA) vilanterol (VI). Two strengths, 100/25mcg and 200/25mcg, have been approved in the US for use in asthma, administered once-daily using the Ellipta dry powder inhaler.

Darrell Baker, SVP & Head, GSK Global Respiratory Franchise, said: “Asthma is a variable condition and guidelines recommend a stepwise approach to treatment with the aim of achieving asthma control. Breo Ellipta is our second asthma treatment to be approved in the US in the past year, and now provides physicians with a range of treatment options delivered via the Ellipta inhaler to meet the needs of appropriate adult patients with differing asthma severities.”

Michael W. Aguiar, President and Chief Executive Officer of Theravance, Inc., said: "We believe the approval of Breo Ellipta as a once-daily ICS/LABA treatment for adults with asthma is a significant catalyst for Theravance, as asthma affects nearly 19 million adults in the US. We are pleased by today’s approval of Breo Ellipta and look forward to making this important medicine available to the appropriate adult patients among those living with the disease.”

The FDA issued a complete response letter related to the proposed use of Breo Ellipta in patients aged 12-17 stating that the data submitted do not show adequate risk-benefit to support the approval in these patients. The FDA stated that additional data would be required to further demonstrate the safety and efficacy in this population.

The efficacy and safety of Breo Ellipta was studied in a clinical trial programme involving over 12,000 subjects in 23 studies of patients aged 12 and over.

Following submission of a supplemental new drug application (sNDA) to the FDA, Breo Ellipta has been approved for the once-daily treatment of asthma in patients aged 18 years and older. 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 hospitalisation in paediatric 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.

About asthma
Asthma is a chronic lung disease that inflames and narrows the airways.1 Approximately 19 million adults in the US currently have asthma.2 Despite medical advances, more than half of patients continue to experience poor control and significant symptoms.3

The causes of asthma are not completely understood but are likely to involve an interaction between a person’s genetic make-up and the environment. Key environmental risk factors for the development of asthma are allergens, respiratory

infections and airway irritants. For more information please see GSK's infographic about adult asthma.

About Breo Ellipta
Breo Ellipta (FF/VI 100/25 mcg) was licensed by the US FDA in May 2013 as a prescription medication for the long-term, once-daily, maintenance treatment of airflow obstruction and for reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. An sNDA for Breo Ellipta in asthma was submitted to the FDA in June 2014 and in April 2015 it was approved for the once-daily treatment of asthma in patients aged 18 years and older. 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 Breo Ellipta.

Important Safety Information (ISI) for 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, 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. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalisation in paediatric and adolescent patients.
When treating patients with asthma, only prescribe Breo Ellipta for patients not adequately controlled on a long-term asthma control medication, such as an ICS, or whose disease severity clearly warrants initiation of treatment with both an ICS 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 ICS. Do not use Breo Ellipta for patients whose asthma is adequately controlled on low- or medium-dose ICS.

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.

Orally inhaled corticosteroids may cause a reduction in growth velocity when administered in children and adolescents.

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.

For asthma, the most common adverse reactions in a 12-week trial (incidence ≥2% and more common than placebo) reported with Breo Ellipta 100/25 (and placebo) were nasopharyngitis 10% (7%), headache 5% (4%), oropharyngeal pain 2% (1%), oral candidiasis 2% (0%), and dysphonia 2% (0%). In a separate 12-week trial the most common adverse reactions (≥2% incidence) reported with Breo Ellipta 100/25 or 200/25 were headache, nasopharyngitis, influenza, upper respiratory tract infection, oropharyngeal pain, sinusitis, bronchitis, and cough. In addition to adverse reactions reported in the 12 week studies, adverse reactions (≥2% incidence) reported with Breo Ellipta 200/25 in a 24-week trial included viral respiratory tract infection, pharyngitis, pyrexia, and arthralgia, and with Breo Ellipta 100/25 or 200/25 in a 12-month trial included pyrexia, back pain, extrasystoles, upper abdominal pain, respiratory tract infection, allergic rhinitis, pharyngitis, rhinitis, arthralgia, supraventricular extrasystoles, ventricular extrasystoles, acute sinusitis, and pneumonia.

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, Inc. – is focused on maximizing the potential value of the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, with the intention of providing capital returns to stockholders. Under the Long-Acting Beta2 Agonist (LABA) Collaboration Agreement with GSK, Theravance is eligible to receive the associated royalty revenues from RELVAR®/BREO® ELLIPTA® (fluticasone furoate/vilanterol, "FF/VI"), ANORO® ELLIPTA® (umeclidinium bromide/vilanterol, "UMEC/VI") and if approved and commercialized, VI monotherapy. Theravance is also entitled to a 15% economic interest in any future payments made by GSK under agreements entered into prior to the spin-off of Theravance Biopharma, and since assigned to Theravance Respiratory Company, LLC, relating to the combination of UMEC/VI/FF and the Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid, and any other product or combination of products that may be discovered and developed in the future under these agreements with GSK (other than RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and VI monotherapy). For more information, please visit Theravance's web site at www.thrxinc.com.

ANORO®, RELVAR®, BREO® and ELLIPTA® are trade marks of the GlaxoSmithKline group of companies.

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)
	Sarah Spencer	+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)
	Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
	Melinda Stubbee	+1 919 483 2510	(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)
Theravance Inc. enquiries:			
Investor Relations	Eric d'Esparbes	+1 650 238 9640	(S. San Francisco)
		investor.relations@thrxinc.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 2014.

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. Such forward-looking statements involve substantial risks, uncertainties and assumptions. Examples of such statements include statements relating to: the commercialization of BREO ELLIPTA in the US, 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 cash dividends or future share repurchases), 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 product candidates through development and commercialization, the timing of seeking regulatory approval of product candidates, 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 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: the disruption of operations during the transition period following the spin-off, including the diversion of managements' and employees' attention, disruption of relationships with collaborators and increased employee turnover, 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 Theravance are described under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Theravance's Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission (SEC) on February 27, 2015. In addition to the risks described above and in Theravance's other filings with the SEC, other unknown or unpredictable factors also could affect Theravance'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. Theravance assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

(THRX-G)

References:

1. Global Initiative for Asthma. Pocket Guide for Asthma Management and Prevention. Updated 2015.
2. Blackwell et al. NHIS, 2012. Vital Health Stat 2014;10(260):19.
3. Demoly et al. Eur Respir Rev. 2012 Mar 1;21(123):66-74. doi: 10.1183/09059180.00008111.

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: April 30, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc