GLAXOSMITHKLINE PLC
Form 6-K
June 30, 2014

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 June 2014

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 30 June 2014, London UK & South San Francisco, CA, USA -LSE Announcement

GSK and Theravance announce submission to US regulatory authorities for fluticasone furoate/vilanterol in asthma

GlaxoSmithKline plc (LSE/NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced the submission of a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) for a fixed dose combination of the inhaled corticosteroid, fluticasone furoate and the long-acting beta2 agonist, vilanterol (FF/VI) as a once-daily treatment for asthma in patients aged 12 years and older, with the brand name of Breo® Ellipta®.

The sNDA is seeking approval for two dose regimens, 100/25mcg and 200/25mcg, administered once daily using the Ellipta dry powder inhaler.

Today's filing is based upon data generated from the comprehensive clinical development programme for FF/VI in asthma. The clinical development programme comprised 48 clinical pharmacology studies in 1,328 subjects and 23 clinical studies in 12,051 patients with asthma, including the Phase III efficacy and safety study of FF/VI reported in December 2013.

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 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. These include allergens such as dust mites and pets.1

About Breo Ellipta in the US
FF/VI 100/25mcg was approved by the US Food and Drug Administration under the brand name Breo Ellipta 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. Breo Ellipta is not indicated for the relief of acute bronchospasm or the treatment of asthma in the US.

Full US prescribing information, including BOXED WARNING and Medication Guide is available at us.gsk.com or US Prescribing Information for Breo Ellipta.

Important Safety Information (ISI) for Breo Ellipta (FF/VI) in COPD in the US
The following ISI is based on the Highlights section of the U.S. Prescribing Information for Breo Ellipta (fluticasone furoate 100 mcg / vilanterol 25 mcg) for the maintenance treatment of airflow obstruction in patients with COPD and to reduce exacerbations of COPD in patients with a history of exacerbations. Please consult the full Prescribing Information for all the labeled safety information for Breo Ellipta.

Long-acting beta2-adrenergic agonists (LABAs), such as vilanterol, one of the active ingredients in Breo Ellipta, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths in subjects receiving salmeterol. This finding with salmeterol is considered a class effect of all LABAs, including vilanterol. In the US, the safety and efficacy of Breo Ellipta in patients with asthma have not been established and therefore Breo Ellipta is not indicated for the treatment of asthma.

Breo Ellipta is contraindicated 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 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 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 Ellipta100 mcg/25 mcg, in clinical trials. There was also an increased incidence of pneumonias resulting in hospitalization. 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 co-administration of Breo Ellipta with long term ketoconazole and other known strong CYP3A4 inhibitors because increased systemic corticosteroid and cardiovascular adverse effects may occur.

As with other inhaled medicines, Breo Ellipta can produce paradoxical bronchospasm which may be life-threatening. 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. 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.

The most common adverse reactions (≥3% and more common than in placebo) reported in two 6-month clinical trials with Breo Ellipta (and placebo) were nasopharyngitis, 9% (8%); upper respiratory tract infection, 7% (3%); headache, 7% (5%); and oral candidiasis, 5% (2%). In addition to the events reported in the 6-month studies, adverse reactions occurring in ≥3% of the subjects treated with Breo Ellipta in two 1-year studies included COPD, back pain, pneumonia, bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, hypertension, influenza, pharyngitis, diarrhea, peripheral edema, and pyrexia.

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

V A Whyte
Company Secretary
30 June 2014

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., A Royalty Management Company - 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 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 its LABA Collaboration Agreement 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.

References

1. Global Initiative for Asthma. Pocket Guide for asthma management and prevention. Updated 2014.
2. Demoly et al. Eur Respir Rev. 2012 Mar 1;21(123):66-74. doi: 10.1183/09059180.00008111.

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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 2013.

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 strategies, plans and objectives of the company following the separation, the timing, manner, amount and planned growth of anticipated potential capital returns to stockholders (including without limitation statements concerning the intention to initiate a cash dividend in the third quarter of 2014, expectations of future cash dividend growth and the potential for 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: 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 heading "Risk Factors" contained in Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 7, 2014 and the risks discussed in Theravance's 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)

Registered in England & Wales:
No. 3888792

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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: June 30, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc