GLAXOSMITHKLINE PLC
Form 6-K
June 11, 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: Wednesday 11 June 2014, London, UK & South San Francisco, CA, USA - LSE Announcement

GSK and Theravance announce positive data from two studies evaluating the efficacy and safety of Incruse™Ellipta® when added to Relvar®/Breo® Ellipta® in patients with COPD

GlaxoSmithKline plc (LSE/NYSE:GSK) and Theravance, Inc. (NASDAQ: THRX) today announced positive results from two phase III studies, which showed that patients with chronic obstructive pulmonary disease (COPD) who received the anticholinergic, Incruse™ Ellipta® (umeclidinium (UMEC) 62.5mcg), or umeclidinium 125mcg (an unlicensed dose) in addition to Relvar®/Breo® Ellipta® (fluticasone furoate/vilanterol, "FF/VI"), an inhaled corticosteroid / long-acting beta2-agonist combination, achieved an additional improvement in lung function (FEV1) compared to patients receiving FF/VI plus placebo.

The studies showed that for the primary endpoint of trough FEV1 at Day 85, the addition of UMEC 62.5mcg or UMEC 125mcg to FF/VI 100/25mcg resulted in a statistically significant improvement in lung function when compared with FF/VI 100/25mcg plus placebo in patients with COPD.

Darrell Baker, SVP and Head, Global Respiratory Franchise, GSK said: "These data are an important addition to the evidence base supporting the efficacy and safety of Incruse. These studies are also the first to investigate the combined effect of two of the newest medicines from our respiratory portfolio, both of which provide 24 hour efficacy. We will continue to progress our research to expand our understanding of how the combined use of these medicines may provide physicians with another treatment approach to meet the individual needs of their patients."

"We are pleased with the positive data from these two studies evaluating an open triple therapy, Incruse added to Relvar/Breo Ellipta," said Rick E Winningham, Chief Executive Officer, Theravance. "With the data reported today, we have further strengthened our understanding of Relvar/Breo Ellipta."

Study designs:
Both studies (200109 and 200110) were 12-week multicentre, randomised, double-blind placebo-controlled studies. 1238 patients with an established clinical history of COPD and an FEV1 of ≤ 70%, were randomised and treated in the studies. Eligible patients were randomised 1:1:1 to receive UMEC 62.5mcg, UMEC 125mcg or placebo added to open-label FF/VI 100/25mcg. All treatments were administered once daily in the dry powder inhaler (DPI), Ellipta®.

The primary endpoint for both studies was trough forced expiratory volume in one second (FEV1) on Day 85.

Studies results:
200109: For the pre-specified primary endpoint of trough FEV1 (Day 85), compared with placebo added to FF/VI 100/25mcg, both UMEC 62.5mcg and UMEC 125mcg added to FF/VI 100/25mcg, produced statistically significant improvements (UMEC 62.5mcg plus FF/VI 100/25 mcg: 124mL difference versus placebo plus FF/VI 100/25mcg; UMEC 125mcg plus FF/VI 100/25 mcg: 128mL difference versus placebo plus FF/VI 100/25mcg, both $p<0.001$).

Incidence of on-treatment adverse events (AEs) were 36% UMEC 62.5mcg + FF/VI 100/25mcg, 39% UMEC 125mcg + FF/VI 100/25mcg, 35% placebo + FF/VI 100/25 mcg. The most frequently reported adverse events (greater than or equal to 3% in any treatment group) were headache, nasopharyngitis, back pain, dysgeusia (an abnormal taste or change in taste), cough, diarrhoea and influenza. The incidence of any cardiovascular adverse events of special interest was 2% UMEC 62.5mcg + FF/VI 100/25mcg, 1% UMEC 125mcg + FF/VI 100/25mcg, 3% placebo + FF/VI 100/25mcg. The incidence of pneumonia in the UMEC 125mcg + FF/VI 100/25mcg and the placebo + FF/VI 100/25mcg groups was 1%. There were no reported cases of pneumonia in the UMEC 62.5mcg + FF/VI 100/25mcg group. One death was reported in the placebo + FF/VI 100/25mcg group and was deemed non drug related by the investigator. There were no deaths reported in the UMEC + FF/VI 100/25mcg treatment groups.

200110: For the pre-specified primary endpoint of Trough FEV1 (Day 85), compared with placebo added to FF/VI 100/25mcg, UMEC 62.5mcg and UMEC 125mcg added to FF/VI 100/25mcg, produced statistically significant improvements (UMEC 62.5mcg plus FF/VI 100/25 mcg: 122mL difference versus placebo plus FF/VI 100/25mcg; UMEC 125 mcg plus FF/VI 100/25 mcg: 111mL difference versus placebo plus FF/VI 100/25mcg, both p<0.001).

Incidence of on-treatment adverse events (AEs) were 33% UMEC 62.5mcg + FF/VI 100/25mcg, 30% UMEC 125mcg + FF/VI 100/25mcg, 39% placebo + FF/VI 100/25mcg. The most frequently reported adverse events (greater than or equal to 3% in any treatment group) were nasopharyngitis, headache and back pain. The incidence of any cardiovascular adverse events of special interest was similar across treatment groups (<1% UMEC 62.5mcg + FF/VI 100/25mcg, 1% UMEC 125mcg + FF/VI 100/25mcg, 3% placebo + FF/VI 100/25mcg). The incidence of pneumonia was the same (<1%) in all treatment groups. Four deaths were reported in the placebo + FF/VI 100/25mcg group and one death was reported in the UMEC 62.5mcg + FF/VI 100/25mcg treatment group. All deaths were deemed non drug related by the investigator.

Umeclidinium 62.5mcg inhalation powder, under the brand name Incruse Ellipta, is only approved for use in the US, Canada and Europe for COPD. It is not approved anywhere else in the world. Umeclidinium 125mcg is not an approved dose anywhere in the world.

The full results of these studies will be posted onto clinicaltrials.gov and presented at a future scientific meeting.

About COPD
Chronic obstructive pulmonary disease (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.

Long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD.1 Cigarette smoke, breathing in second-hand smoke, air pollution, chemical fumes or dust from the environment or workplace can all contribute to COPD. 1 Most people who have COPD are at least 40 years old when symptoms begin.

About Incruse Ellipta
Incruse Ellipta is an anticholinergic (also known as a long-acting muscarinic antagonist or LAMA) approved in the US for the long-term once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. Incruse contains 62.5mcg umeclidinium delivered by the Ellipta inhaler.

Full US Prescribing Information including Patient Information Leaflet is available at us.gsk.com.

Incruse Ellipta is approved in Europe as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). For the EU Summary of Product Characteristics for Incruse Ellipta, please visit: http://ec.europa.eu/health/documents/community-register/html/h922.htm

Important Safety Information for Umeclidinium (Incruse Ellipta) in the US
The following Important Safety Information is based on the Highlights section of the Prescribing Information for Incruse Ellipta. Please consult the full Prescribing Information for all the labeled safety information for Incruse Ellipta.

Incruse Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins or who have hypersensitivity to either umeclidinium, or any of the other ingredients.

Incruse 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, which should be treated with an

inhaled, short-acting beta2-agonist.

Incruse Ellipta can produce paradoxical bronchospasm, which may be life-threatening.

Incruse Ellipta should be used with caution in patients with narrow-angle glaucoma. Instruct patients to contact a physician immediately should any signs or symptoms of narrow-angle glaucoma occur.

Incruse Ellipta should be used with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder neck obstruction. Instruct patients to contact a physician immediately should any signs or symptoms of urinary retention occur.

The most common adverse reactions (incidence ≥2% and more common than placebo) with Incruse Ellipta (and placebo) were nasopharyngitis, 8% (7%); upper respiratory tract infection, 5% (4%); cough, 3% (2%); and arthralgia, 2% (1%). Other adverse reactions with Incruse Ellipta observed with an incidence less than 1% but more common than placebo included atrial fibrillation.

Avoid co-administration of Incruse Ellipta with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects such as worsening of narrow-angle glaucoma, and worsening of urinary retention.

About Relvar/Breo Ellipta
Breo® Ellipta® (FF/VI 100/25mcg) is an inhaled corticosteroid / long-acting beta2-agonist combination (ICS/LABA) approved in the US for the long-term, once-daily, maintenance treatment of airflow obstruction 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 Breo Ellipta.

Relvar Ellipta (FF/VI 100/25 mcg and 200/25 mcg) is approved in Japan for the treatment of asthma.
Relvar Ellipta is not indicated for the treatment of COPD in Japan.

Relvar Ellipta is approved in Europe for 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. One strength has been licensed for the treatment of COPD (92/22 mcg) and is administered once-daily using Ellipta, a dry powder inhaler (DPI).
For the EU Summary of Product Characteristics for Relvar Ellipta, please visit:
http://ec.europa.eu/health/documents/community-register/html/h886.htm

Important Safety Information (ISI) for Breo Ellipta (FF/VI) in the US

The following ISI is based on the Highlights section of the U.S. Prescribing Information for Breo Ellipta. 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 coadministration 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®, INCRUSE™, ANORO™ and ELLIPTA® are trade marks of the GlaxoSmithKline group of companies.

V A Whyte
Company Secretary
11 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 - 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 and the Strategic Alliance 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 its agreements with 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.

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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 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 Chronic Obstructive Lung Disease (GOLD). Pocket guide to COPD diagnosis, management and prevention

Registered in England & Wales:
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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: June 11, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc