

GLAXOSMITHKLINE PLC
Form 6-K
December 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 December 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 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

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Issued: 18th December 2013, London UK and South San Francisco, CA, USA - LSE Announcement

ANORO™ ELLIPTA™ approved as first once-daily dual bronchodilator for the treatment of COPD in the US

GlaxoSmithKline plc (LSE/NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the US Food and Drug Administration (FDA) has approved ANORO™ ELLIPTA™ as a combination anticholinergic/long-acting beta2-adrenergic agonist (LABA) indicated 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. Anoro Ellipta is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

Anoro Ellipta (umeclidinium and vilanterol inhalation powder) is the first once-daily product approved in the US that combines two long-acting bronchodilators in a single inhaler for the maintenance treatment of COPD. The FDA-approved strength is umeclidinium/vilanterol 62.5 mcg/25 mcg.

Darrell Baker, SVP & Head, GSK Global Respiratory Franchise, said: "We believe Anoro Ellipta will be an important treatment option for appropriate patients with COPD. It is the first combination product approved in the US that delivers two once-daily bronchodilators in a single inhaler. This approval is a significant achievement for GSK."

"We are very pleased that Anoro Ellipta has become the first once-daily dual bronchodilator approved in the US for the treatment of COPD," said Rick E Winningham, Chief Executive Officer of Theravance. "This is a significant milestone for Theravance and GSK and is testament to our ongoing partnership and shared commitment to the development of respiratory medicines."

Following this approval by the FDA, it is anticipated that launch activities in the US will commence during the first quarter of 2014. Under the terms of the 2002 LABA collaboration agreement, Theravance is obligated to make a milestone payment of \$30 million (USD) to GSK following FDA approval of Anoro Ellipta. A further \$30 million (USD) payment to GSK will follow the launch of Anoro Ellipta in the US.

The phase III pivotal programme for Anoro Ellipta included seven clinical studies with almost 6,000 patients with COPD.

B Kelly-Bisla
Corporate Secretariat
18 December 2013

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. The National Heart, Lung and Blood Institute (NHLBI) estimates that nearly 27 million people in the US alone are affected by COPD.i

According to the NHLBI, long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD. In the United States, the most common irritant that causes COPD is cigarette smoke. Breathing in second hand smoke, air pollution, chemical fumes or dust from the environment or workplace also can contribute to COPD. Most people who have COPD are at least 40 years old when symptoms begin.

About Anoro Ellipta

Anoro Ellipta is the first once-daily anticholinergic/LABA combination product 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. Anoro Ellipta is not indicated for the relief of acute bronchospasm or for the treatment of asthma. Anoro contains 62.5 mcg umeclidinium, an anticholinergic, and 25 mcg vilanterol, a LABA, in a single inhaler, the Ellipta.

Full US Prescribing Information, including BOXED WARNING and Medication Guide will be available soon at: us.gsk.com. 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.

Important Safety Information for Anoro Ellipta

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

Long-acting beta2-adrenergic agonists (LABAs), such as vilanterol, one of the active ingredients in Anoro 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. The safety and efficacy of Anoro Ellipta in patients with asthma have not been established. Anoro Ellipta is not indicated for the treatment of asthma.

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

Anoro 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.

Anoro Ellipta should not be used more often than recommended, at higher doses than recommended, or in conjunction with additional medicine containing a LABA, as an overdose may result.

Anoro Ellipta should be used with caution when considering coadministration with long-term ketoconazole and other known strong cytochrome P450 3A4 inhibitors because increased cardiovascular adverse effects may occur.

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

Anoro Ellipta should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Anoro 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.

Anoro 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.

Anoro 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.

Beta-adrenergic agonist medicines may produce significant hypokalemia and transient hyperglycemia in some patients.

The most common adverse reactions (incidence $\geq 1\%$ and more common than placebo) reported in four 6-month clinical trials with Anoro Ellipta (and placebo) were pharyngitis, 2% ($<1\%$); sinusitis 1% ($<1\%$); lower respiratory tract infection, 1% ($<1\%$); constipation, 1% ($<1\%$); diarrhea, 2% (1%); pain in extremity 2% (1%); muscle spasms, 1% ($<1\%$); neck pain, 1% ($<1\%$); and chest pain 1% ($<1\%$). In addition to the 6-month efficacy trials with Anoro Ellipta, a 12-month trial evaluated the safety of umeclidinium/vilanterol 125 mcg/25 mcg in subjects with COPD. Adverse reactions (incidence $\geq 1\%$ and more common than placebo) in subjects receiving umeclidinium/vilanterol 125 mcg/25 mcg were: headache, back pain, sinusitis, cough, urinary tract infection, arthralgia, nausea, vertigo, abdominal pain, pleuritic pain, viral respiratory tract infection, toothache, and diabetes mellitus.

Use of beta2-agonists, such as vilanterol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists on the cardiovascular system may be potentiated.

Use beta blockers with caution as they not only block the pulmonary effect of beta agonists, such as vilanterol, but may produce severe bronchospasm in patients with COPD.

Use with caution in patients taking non-potassium-sparing diuretics, as electrocardiographic changes and/or hypokalemia associated with non-potassium-sparing diuretics may worsen with concomitant beta-agonists.

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

Other Umeclidinium/Vilanterol Regulatory Activity:

Regulatory applications for UMEC/VI have been submitted and are undergoing assessment in a number of countries, including across the European Union and Japan. Umeclidinium/vilanterol is not licensed anywhere outside of the US.

Other Respiratory Development Programmes:

The GSK respiratory development portfolio also includes VI monotherapy and MABA (GSK961081), developed in collaboration with Theravance, as well as GSK's investigational medicines FF monotherapy, UMEC monotherapy and anti-IL5 MAb (mepolizumab). These investigational medicines are not currently approved anywhere in the world.

ANORO and ELLIPTA are trademarks of the GSK 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), 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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Theravance Inc.

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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.

(THR-X-G)

References

[i] National Heart, Lung, and Blood Institute. 2012 Chart Book on Cardiovascular, Lung, and Blood Diseases. February 2012 http://www.nhlbi.nih.gov/resources/docs/2012_ChartBook_508.pdf
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: December 18, 2013

By: SIMON BICKNELL

Simon Bicknell
Authorised Signatory for and on
behalf of GlaxoSmithKline plc