GLAXOSMITHKLINE PLC
Form 6-K
February 20, 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 February 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: Thursday 20 February 2014, London UK

Anoro®(umeclidinium / vilanterol) receives positive opinion from the CHMP in Europe for the treatment of COPD

GlaxoSmithKline plc (LSE/NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP)has issued a positive opinion recommending marketing authorisation for umeclidinium/vilanterol (UMEC/VI) under the proposed brand name Anoro® as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Anoro is a combination of UMEC, a long-acting muscarinic antagonist (LAMA) and VI, a long-acting beta2 agonist (LABA) in a single inhaler, the Ellipta®. The proposed strength is UMEC/VI 55mcg / 22 mcg.

Patrick Vallance, GSK's President of Pharmaceuticals R&D, said, "COPD affects millions of people across Europe and GSK is committed to developing new therapeutic options that could help these patients. Today's positive opinion is a step towards us making this important new medicine available. We are looking forward to the final decision of the European Commission in the near future."

"We are pleased with the positive opinion which brings UMEC/VI closer to approval in Europe," said Rick E Winningham, Chief Executive Officer of Theravance. "This is an important milestone and reflects the ongoing efforts of the collaboration between Theravance and GSK to research and develop new respiratory medicines that meet patient needs."

A CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission. A final decision by the European Commission is anticipated during the second quarter of 2014.

The phase III pivotal programme for UMEC/VI included seven clinical studies with almost 6,000 patients with COPD.

In December 2013, Anoro™ Ellipta™ 62.5mcg / 25mcg was approved for use in appropriate patients with COPD by both the US Food and Drug Administration and Health Canada. In Europe, the UMEC/VI strength of 55mcg / 22mcg is specified as the delivered dose (emitted from the inhaler) which is equivalent to the 62.5mcg / 25mcg pre-dispensed dose (contained inside the inhaler) approved in the US and Canada.

Anoro Ellipta is not indicated for the relief of acute bronchospasm or for the treatment of asthma. Full US prescribing information, including BOXED WARNING and Medication Guide are available at: http://us.gsk.com/products/assets/us_anoro_ellipta.pdf.

In April 2013, a regulatory submission for UMEC/VI under the trade name Anoro Ellipta was filed in Japan and is currently under review.

UMEC/VI is an investigational medicine and is not currently approved anywhere in the world outside of the US and Canada.

Important Safety Information for UMEC/VI
UMEC/VI is contraindicated in patients with hypersensitivity to either umeclidinium, vilanterol, or any of the excipients.

UMEC/VI should not be used in patients with asthma since it has not been studied in this patient population. Administration of UMEC/VI may produce paradoxical bronchospasm that may be life-threatening. UMEC/VI is not

indicated for the treatment of acute episodes of bronchospasm.

In the event of deterioration of COPD during treatment with UMEC/VI, a re-evaluation of the patient and of the COPD treatment regimen should be undertaken.

Cardiovascular effects, such as cardiac arrhythmias e.g. atrial fibrillation and tachycardia, may be seen after the administration of muscarinic receptor antagonists and sympathomimetics, including UMEC/VI. Patients with clinically significant uncontrolled cardiovascular disease were excluded from clinical studies. Therefore, UMEC/VI should be used with caution in patients with severe cardiovascular disease.

Consistent with its antimuscarinic activity, UMEC/VI should be used with caution in patients with urinary retention or with narrow-angle glaucoma.

Beta2-adrenergic agonists may produce significant hypokalaemia in some patients, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. No clinically relevant effects of hypokalaemia were observed in clinical studies with UMEC/VI at the proposed dosage strength of 55mcg/22mcg. Caution should be exercised when UMEC/VI is used with other medicinal products that also have the potential to cause hypokalaemia.

Beta2-adrenergic agonists may produce transient hyperglycemia in some patients. No clinically relevant effects on plasma glucose were observed in clinical studies with UMEC/VI at the proposed dosage strength of 55mcg/22mcg. Upon initiation of treatment with UMEC/VI, plasma glucose should be monitored more closely in diabetic patients.

UMEC/VI should be used with caution in patients with convulsive disorders or thyrotoxicosis and in patients who are unusually responsive to beta2-adrenergic agonists.

UMEC/VI contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take UMEC/VI.

The most frequently reported adverse reaction with UMEC/VI was nasopharyngitis (9%). Other common adverse reactions (reported with a frequency of ≥1/100 to <1/10) include: urinary tract infection, sinusitis, pharyngitis, upper respiratory tract infection, headache, cough, oropharyngeal pain, constipation and dry mouth.

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Corporate Secretariat
20 February 2014

Other Respiratory Development Programmes:
The GSK respiratory development portfolio also includes investigational VI monotherapy and MABA (GSK961081), developed in collaboration with Theravance, as well as GSK's investigational medicines fluticasone furoate 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 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®/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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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)

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: February 20, 2014

By: SIMON BICKNELL

Simon Bicknell
Authorised Signatory for and on
behalf of GlaxoSmithKline plc