GLAXOSMITHKLINE PLC
Form 6-K
September 11, 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 September 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 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: 10th September 2013, London UK and South San Francisco, CA, USA

FDA Advisory Committee recommends approval in US of umeclidinium/vilanterol for the treatment of COPD

GlaxoSmithKline plc (LSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the Pulmonary-Allergy Drugs Advisory Committee (PADAC) to the US Food and Drug Administration (FDA) voted 11 yes to 2 no that the efficacy and safety data provide substantial evidence to support approval of umeclidinium/vilanterol (UMEC/VI, 62.5/25mcg dose) for the long-term, once-daily, maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

ANORO™ ELLIPTA™ is the proposed proprietary name for UMEC/VI, a combination of two investigational bronchodilator molecules - GSK573719 or umeclidinium bromide (UMEC), a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta2 agonist (LABA), administered using the ELLIPTA™ inhaler.

The FDA Advisory Committee also voted that the safety of the investigational medicine has been adequately demonstrated at the 62.5/25mcg dose for the proposed indication (10 yes, 3 no), and the efficacy data provided substantial evidence of a clinically meaningful benefit for UMEC/VI 62.5/25mcg once daily for the long-term, maintenance treatment of airflow obstruction in COPD (13 yes, 0 no).

Patrick Vallance, GSK's President of Pharmaceuticals R&D, said: "Today's recommendation is good news and a reflection of our commitment to giving an alternative treatment option for patients living with COPD - a disease that affects millions of Americans. If approved, Anoro Ellipta will be the first, once-daily dual bronchodilator available in the US, marking another significant milestone for GSK's portfolio of medicines to treat respiratory disease. We will continue to work with the FDA as they complete their review."

"We are pleased with the Advisory Committee's support of UMEC/VI," said Rick E Winningham, Chief Executive Officer of Theravance. "This is a transformative year for Theravance and today's positive recommendation brings the second major respiratory medicine in our GSK collaboration closer to approval and becoming an important therapeutic option for COPD patients."

In December 2012, a New Drug Application (NDA) was submitted to the FDA for the use of UMEC/VI administered by the ELLIPTA™ inhaler for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. UMEC/VI is not proposed for the relief of acute bronchospasm or for the treatment of asthma in any of the regulatory applications.

The FDA Advisory Committee provides non-binding recommendations for consideration by the FDA, with the final decision on approval made by the FDA. The Prescription Drug User Fee Act (PDUFA) goal date for UMEC/VI is 18 December 2013.

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

Safety Information
Across the four pivotal COPD studies for UMEC/VI, the most frequently reported adverse eventsacross all treatment arms, including placebo, were headache, nasopharyngitis, cough, upper respiratory tract infection, and back pain. COPD exacerbation was the most common serious adverse event reported. In addition, in the four pivotal COPD

studies, a small imbalance was observed in cardiac ischemia which was not observed in the long term safety study.

The UMEC/VI clinical development programme involved over 6,000 COPD patients.

S M Bicknell
Company Secretary

10 September 2013

About COPD
Chronic obstructive pulmonary disease (COPD) is a term referring to two lung diseases, chronic bronchitis and emphysema, that are characterized by obstruction to airflow that interferes with normal breathing. COPD is the third most common cause of death in the US and The National Heart, Lung and Blood Institute (NHLBI) estimates that nearly 15 million US adults have COPD and another 12 million are undiagnosed or developing COPD[i].

According to the NHLI, long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD and in the United States, the most common irritant that causes COPD is cigarette smoke. Breathing in second hand smoke, air pollution, or 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.

Other Respiratory Development Programmes:
Anoro Ellipta is one of several late-stage assets in the GSK respiratory development portfolio. The GSK respiratory development portfolio also includes VI monotherapy and MABA (GSK961081), developed in collaboration with Theravance, as well as GSK's investigational medicines fluticasone furoate (FF) monotherapy, UMEC monotherapy and anti-IL5 MAb (mepolizumab). These investigational medicines are not currently approved anywhere in the world.

GlaxoSmithKline - 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

ANORO™ ELLIPTA™, BREO™ ELLIPTA™ and RELVAR™ ELLIPTA™ are trademarks of the GlaxoSmithKline group o companies. The use of ANORO™ ELLIPTA™ and RELVAR™ ELLIPTA™ brand names is not approved by any regulatory authorities.

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 Muscar 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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GlaxoSmithKline 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)
US Media enquiries:	Stephen Rea	+1 215 751 4394	(Philadelphia)
	Kevin Colgan	+1 919 483 2933	(North Carolina)
	Melinda Stubbee	+1 919 483 2510	(North Carolina)
	Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
	Sarah Alspach	+1 202 715 1048	(Washington, DC)
	Jennifer Armstrong	+1 215 751 5664	(Philadelphia)
Analyst/Investor enquiries:	Ziba Shamsi	+ 44 (0) 20 8047 3289	(London)
	Lucy Budd	+44 (0) 20 8047 2248	(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@theravance.com Michael W. Aguiar +1 650 808 4100 (San Francisco)

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 August 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

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

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: September 11, 2013

By: SIMON BICKNELL

Simon Bicknell
Authorised Signatory for and on
behalf of GlaxoSmithKline plc