

GLAXOSMITHKLINE PLC

Form 6-K

January 09, 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 January 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

--

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

--

Issued: 9 January 2013, London UK and South San Francisco, CA, USA - LSE Announcement

GSK and Theravance announce regulatory submission for ANORO™ (UMEC/VI) in Europe

GlaxoSmithKline plc (LSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced the submission of a regulatory application in the European Union for the investigational once-daily LAMA/LABA combination medicine, UMEC/VI, for patients with chronic obstructive pulmonary disease (COPD). On 18th December 2012, GSK and Theravance announced the submission of a regulatory application in the United States (US) for UMEC/VI, for patients with COPD.

UMEC/VI is 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.

**European Submission:**

A Marketing Authorisation Application (MAA) for UMEC/VI (55/22mcg and 113/22mcg doses), with the proposed proprietary name ANORO™, has been submitted to the European Medicines Agency (EMA) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. The UMEC/VI doses of 55/22mcg and 113/22mcg are specified as the delivered doses (emitted from the inhaler) which are equivalent to the 62.5/25mcg and 125/25mcg pre-dispensed doses (contained inside the inhaler) submitted for approval in the US.

**Future Regulatory Submissions:**

Regulatory submissions for UMEC/VI are planned in other countries during the course of 2013. In addition, GSK intends to commence global regulatory submissions for UMEC monotherapy later this year.

**Other Respiratory Development Programmes:**

UMEC/VI is one of several late-stage assets in the GSK respiratory development portfolio, which includes fluticasone furoate/vilanterol (FF/VI, with proposed brand names RELVAR™ and BREO™), 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™, RELVAR™, BREO™ and ELLIPTA™ are trademarks of the GlaxoSmithKline group of companies. The use of these brand names is not approved by any regulatory authorities.

V A Whyte  
Company Secretary  
9 January 2013

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](http://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

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

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 programs include: RELVAR™ or BREO™ (FF/VI), ANORO™ (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist program. 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](http://www.theravance.com).

THERAVANCE®, the Theravance logo, and MEDICINES THAT MAKE A DIFFERENCE® are registered trademarks of Theravance, Inc.

GlaxoSmithKline

Enquiries:

UK Media enquiries:	David Mawdsley	+44 (0) 20 8047 5502	(London)
	Sarah Spencer	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
	Catherine Hartley	+44 (0) 20 8047 5502	(London)
	Alex Harrison	+44 (0) 20 8047 5502	(London)
	US Media enquiries:	Stephen Rea	+1 215 751 4394
Mary Rhyne		+1 919 483 0492	(North Carolina)
Sarah Alspach		+1 202 715 1048	(Washington, DC)
Analyst/Investor enquiries:	Sally Ferguson	+44 (0) 20 8047 5543	(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)
	Ziba Shamsi	+ 44 (0) 20 8047 3289	(London)

Theravance Inc. Enquiries:

[investor.relations@theravance.com](mailto:investor.relations@theravance.com) Michael W. Aguiar +1 650 808 4100 (San Francisco)

GlaxoSmithKline cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, 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 'Risk factors' in the 'Financial review & risk' section in the company's Annual Report 2011 included as exhibit 15.2 to the company's Annual Report on Form 20-F for 2011.

#### 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 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. 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, the potential that results of clinical or non-clinical studies indicate product candidates are unsafe or ineffective, 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 October 31, 2012 and the risks discussed in our other period filings with 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.

#### 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 authorized.

GlaxoSmithKline plc  
(Registrant)

Date: January 9, 2013

By: VICTORIA WHYTE

-----

Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc