

GLAXOSMITHKLINE PLC

Form 6-K

June 02, 2016

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 02 June 2016

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: Thursday 2 June 2016, London UK - LSE Announcement

Regulatory update on US filing plans for closed triple combination therapy FF/UMEC/VI in patients with COPD

Acceleration of filing of US New Drug Application now expected by end of 2016

GlaxoSmithKline plc (LSE:GSK) and Innoviva, Inc (Nasdaq: INVA) today announced that, following discussions with the US Food and Drug Administration (FDA), GSK has brought forward the plan to file a New Drug Application (NDA) in the US for the once-daily closed triple combination therapy, fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI; a combination inhaled corticosteroid, long-acting muscarinic antagonist, long-acting beta agonist) for patients with chronic obstructive pulmonary disease (COPD). The US regulatory submission is now anticipated by the end of 2016, rather than the first half of 2018, as previously expected.

The NDA for the closed triple combination therapy will comprise data now in hand from the closed triple combination therapy development programme, as well as data from studies with FF, UMEC and VI either alone or in combination.

The companies continue to expect an EU regulatory submission of the closed triple combination therapy for COPD by the end of 2016.

#### About closed triple therapy

The closed triple therapy is a combination of three molecules: fluticasone furoate (FF), an inhaled corticosteroid (ICS), umeclidinium (UMEC), an anti-cholinergic, also known as a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta2-adrenergic agonist (LABA) delivered once-daily in GSK's Ellipta® dry powder inhaler.

#### About the ongoing clinical programme in COPD

The ongoing clinical programme in patients with COPD comprises two studies investigating the effectiveness and safety of closed triple therapy compared to existing COPD treatments.

The FULFIL (Lung FUnction and quality of LiFe assessment in COPD with closed trIpLe therapy) study, which began in 2015 and is expected to read out later in 2016 to support EU filing, is assessing whether the closed triple therapy can improve lung function and health-related quality of life compared with Symbicort® (budesonide/formoterol), a twice-daily ICS/LABA combination delivered via the Turbohaler® inhaler.

The IMPACT (InforMing the PATHway of COPD Treatment) study, which began in 2014 and is expected to read out in 2017, is investigating whether FF/UMEC/VI can reduce the rate of exacerbations compared with two, once-daily dual therapies from GSK's existing portfolio: FF/VI, an ICS/LABA combination and UMEC/VI, a LAMA/LABA combination.

The closed triple combination of FF/UMEC/VI is not approved for use anywhere in the world.

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](http://www.gsk.com).

Innoviva - Innoviva is focused on bringing compelling new medicines to patients in areas of unmet need by leveraging its significant expertise in the development, commercialization and financial management of bio-pharmaceuticals. Innoviva's portfolio is anchored by the respiratory assets partnered with Glaxo Group Limited (GSK), including

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RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, which were jointly developed by Innoviva and GSK. Under the agreement with GSK, Innoviva is eligible to receive associated royalty revenues from RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and, if approved and commercialized, VI monotherapy, as well. In addition, Innoviva retains a 15 percent economic interest in future payments made by GSK for earlier-stage programs partnered with Theravance Biopharma, Inc., including the closed triple combination therapy for COPD. For more information, please visit Innoviva's website at [www.inva.com](http://www.inva.com).

RELVAR®, BREO®, ANORO® and ELLIPTA® are trademarks of the GlaxoSmithKline group of companies. SYMBICORT® and TURBOHALER® are trademarks of AstraZeneca.

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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. 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 2015.

Innoviva forward-looking statements

This press release contains certain "forward-looking" statements. Such forward-looking statements involve substantial risks, uncertainties and assumptions. Examples of such statements include statements relating to: the development, regulatory and commercial plans for closed triple combination therapy, the commercialization of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® in the jurisdictions in which these products have been approved; the strategies, plans and objectives of the company (including the company's growth strategy and corporate development initiatives beyond the existing respiratory portfolio); the timing, manner, amount and planned growth of anticipated potential capital returns to stockholders (including, without limitation, statements regarding the company's expectations of future share purchases and future cash dividends); 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 regulatory approval of product candidates; projections of revenue, expenses and other financial items; and risks related to the implementation of our share repurchase program as currently contemplated. These statements are based on the current estimates and assumptions of the management of Innoviva 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 Innoviva 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: lower than expected future royalty revenue from respiratory products partnered with GSK, 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 Innoviva are described under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Innoviva's Annual Report on Form 10-K for the year ended December 31, 2015 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at [www.sec.gov](http://www.sec.gov). Additional information will also be set forth in those sections of Innoviva's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, which will be filed with the SEC in the third quarter of 2016. In addition to the risks described above and in Innoviva's other filings with the SEC, other unknown or unpredictable factors also could affect Innoviva's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Innoviva assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

Registered in England & Wales:

No. 3888792

Registered Office:

980 Great West Road

Brentford, Middlesex

TW8 9GS

SIGNATURES

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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 02, 2016

By: VICTORIA WHYTE  
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Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc