GLAXOSMITHKLINE PLC
Form 6-K
September 06, 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 06 September 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 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

Issued: Tuesday, 6 September 2016, London UK - LSE Announcement

GSK presents positive results from phase III FULFIL study of closed triple combination therapy FF/UMEC/VI versus Symbicort® Turbohaler® in COPD at ERS International Congress

- Improvements in lung function and health-related quality of life supported by statistically significant reductions in exacerbations

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced the presentation of further data from the pivotal phase III FULFIL study with investigational closed triple combination therapy fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI 100/62.5/25 mcg) in patients with chronic obstructive pulmonary disease (COPD), at the European Respiratory Society International Congress taking place in London this week.

The FULFIL study was designed to evaluate the effects of once daily FF/UMEC/VI compared with twice daily Symbicort® Turbohaler® (budesonide/formoterol 400/12 mcg) in patients with advanced COPD.

The study, which reported headline results in June 2016, met its two co-primary endpoints. At 24 weeks, there was a clinically meaningful and statistically significant ($p<0.001$) benefit for FF/UMEC/VI in both lung function, measured as mean change from baseline in trough FEV1 (171mL, 95% confidence interval [148, 194]) and health-related quality of life, measured as mean change from baseline in St George's Respiratory Questionnaire (SGRQ) total score (-6.6 units for closed triple versus -4.3 units for budesonide/formoterol, difference of -2.2 units, 95% confidence interval [-3.5, -1.0]). In addition, the proportion of patients who responded with the minimum clinically important difference in SGRQ (-4 units) was 50% on closed triple and 41% on budesonide/formoterol (odds ratio 1.41; $p<0.001$).

This benefit of treatment with closed triple therapy was also observed in the subset of patients who received treatment for up to 52 weeks, with a statistically significant improvement of 179mL in trough FEV1 and a numerical improvement of -2.7 units in SGRQ total score at Week 52 with closed triple therapy compared with budesonide/formoterol.

The study also showed a statistically significant and clinically meaningful reduction in the annual rate of moderate/severe exacerbations with closed triple therapy compared to budesonide/formoterol, with closed triple therapy showing a 35% reduction versus budesonide/formoterol based on data up to 24 weeks ($p=0.002$) and a 44% reduction in the subset of patients that received treatment for up to 52 weeks ($p=0.006$).

The safety profile of the closed triple combination up to 24 weeks and in the subset of patients up to 52 weeks was consistent with the known profile of the individual medicines and their combinations. Up to both 24 weeks and 52 weeks, the most common adverse events in both treatment arms were nasopharyngitis, headache and COPD worsening.

The incidence of investigator-reported serious adverse events for closed triple and budesonide/formoterol, respectively, was 5.4% and 5.7% up to 24 weeks, and 10.0% and 12.7% up to 52 weeks. Up to 24 weeks, the incidence of pneumonia was 1.0% in the closed triple arm and 0.3% in the budesonide/formoterol arm. Up to 52 weeks, it was 1.9% in the closed triple arm and 1.8% in the budesonide/formoterol arm.

Dave Allen, Head of Respiratory R&D at GSK, commented: "Exacerbations are a major cause of morbidity in COPD and reducing these symptomatic and potentially life-threatening episodes is a priority for physicians. To observe such significant reductions in exacerbations with closed triple therapy versus budesonide/formoterol is encouraging and supports our belief that a convenient, once-daily triple therapy dosing option delivered via a single inhaler could provide compelling and clinically important treatment benefits in this more severe patient population."

Mike Aguiar, CEO of Innoviva, Inc, added: "The results of the FULFIL study confirm that the closed triple therapy of FF/UMEC/VI is superior to dual therapy of budesonide/formoterol on the key measures of lung function, quality of life and exacerbation reduction. These results contribute to the medicine's positive benefit/risk profile and increase understanding of the clinical value of triple therapy in those patients that physicians decide would benefit from triple therapy versus dual therapy alone."

GSK's plans are on schedule for regulatory submissions of the closed triple combination therapy for COPD in the US and Europe by the end of 2016.

About the closed triple therapy

The closed triple therapy is a combination of three medicines: fluticasone furoate (FF), an inhaled corticosteroid (ICS), umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta2-adrenergic agonist (LABA) delivered once-daily in GSK's Ellipta® inhaler. The FULFIL study compared FF/UMEC/VI with budesonide and formoterol, an ICS/LABA combination delivered twice-daily in the Turbohaler dry powder inhaler.

About FULFIL

FULFIL (Lung Function and quality of Life assessment in COPD with closed trIpLe therapy) was a randomised, double-blind, double-dummy, parallel group multicentre study evaluating once-daily FF/UMEC/VI (100mcg/62.5mcg/ 25mcg) inhalation powder versus twice-daily budesonide/formoterol (400mcg/12mcg) via the Turbohaler dry powder inhaler. In the study, 1,810 patients were treated across 162 study centres globally (911 on FF/UMEC/VI and 899 on budesonide/formoterol). The population included symptomatic COPD patients (COPD assessment test ≥ 10) with either an FEV1 of less than 50% predicted, or FEV1 of 50% to less than 80% of predicted and two moderate or one severe exacerbation in the prior year.

The co-primary endpoints were: change from baseline in trough FEV1 and SGRQ total score after 24 weeks of treatment. Other endpoints included the effect of FF/UMEC/VI on the annual rate of moderate/severe exacerbations compared with budesonide/formoterol, and the safety profile of FF/UMEC/VI compared with budesonide/formoterol over 24 weeks and 52 weeks of treatment. To provide additional longer term safety data, a sub-set of 430 patients remained on blinded study treatment for up to a total of 52 weeks.

About the ongoing clinical programme in COPD

In addition to FULFIL, the IMPACT (InforMing the PAthway of COPD Treatment) study, which began in 2014 and is expected to complete 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: Relvar/Breo (FF/VI), an ICS/LABA combination, and Anoro (UMEC/VI), a LAMA/LABA combination.

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

About COPD

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. COPD is thought to affect 329 million people worldwide. Long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD. Cigarette smoke, breathing in second hand smoke, air pollution, chemical fumes or dust from the environment or workplace can all contribute to COPD. Most people who have COPD are at least 40 years old when symptoms begin.

About Symbicort Turbohaler - http://www.medicines.org.uk/emc/medicine/11882

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 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.

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.

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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 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. Innoviva 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. 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; and projections of revenue, expenses and other financial items;. 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 June 30, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. 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. (INVA-G)

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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: September 06, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc