GLAXOSMITHKLINE PLC
Form 6-K
September 20, 2017

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 20 September 2017

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: 20 September 2017, London UK - LSE Announcement

GSK and Innoviva report positive headline results from IMPACT study showing single inhaler triple therapy Trelegy Ellipta reduced COPD exacerbations

Trelegy Ellipta met study primary endpoint demonstrating reduction in exacerbations compared with the dual therapies Anoro Ellipta and
Relvar/Breo Ellipta in patients with COPD

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced positive headline results from the landmark phase III IMPACT study of Trelegy Ellipta, the first and only FDA approved once-daily single inhaler triple therapy comprising an inhaled corticosteroid (ICS), long-acting muscarinic antagonist (LAMA) and long-acting beta agonist (LABA).

Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol, FF/UMEC/VI) is approved for the long-term, once-daily, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD) who are receiving Breo (fluticasone furoate/vilanterol, FF/ VI) and
require additional bronchodilation or who are receiving Breo and Incruse
(umeclidinium, UMEC).

The IMPACT study, which involved 10,355 patients, met its primary endpoint demonstrating statistically significant reductions in the annual rate of on-treatment moderate/severe exacerbations for FF/UMEC/VI (100/62.5/25mcg) when compared with two, once-daily dual COPD therapies from GSK's existing portfolio. The study showed a:

- 15% reduction for FF/UMEC/VI compared with Relvar/Breo Ellipta (FF/VI,100/25mcg); 0.91 vs 1.07 per year; $p<0.001$

- 25% reduction for FF/UMEC/VI compared with Anoro Ellipta (UMEC/VI, 62.5/25mcg); 0.91 vs 1.21 per year; $p<0.001$

In addition, statistically significant improvements were observed across all pre-specified key secondary endpoints and associated treatment comparisons:

- Change from baseline trough FEV1 at week 52 for FF/UMEC/VI compared with FF/VI was 97mL; $p<0.001$ and for FF/UMEC/VI compared with UMEC/VI was 54mL; $p<0.001$

- Change from baseline St George's Respiratory Questionnaire at week 52 for FF/UMEC/VI compared with FF/VI was -1.8 units; $p<0.001$ and for FF/UMEC/VI compared with UMEC/VI was -1.8 units; $p<0.001$

- Analysis of time to first on-treatment moderate/severe COPD exacerbation demonstrated a 14.8% reduction in risk for FF/UMEC/VI compared with FF/VI; $p<0.001$, and a 16.0% reduction in risk for FF/UMEC/VI compared with UMEC/VI; $p<0.001$

Based on review of the headline data, the safety profile of FF/UMEC/VI was consistent with the known profile of the individual medicines and their dual combinations. The most common adverse events across the treatment groups were

viral upper respiratory tract infection, worsening of COPD, upper respiratory tract infection, pneumonia and headache. The incidences of the most frequent serious adverse events were worsening of COPD: 11%, 11% and 13% for FF/UMEC/VI, FF/VI and UMEC/VI, respectively; and pneumonia: 4%, 4% and 3% for FF/UMEC/VI, FF/VI and UMEC/VI, respectively.

Patrick Vallance, President R&D, GSK, said: "We are delighted with the positive results achieved in the IMPACT study. This is the first study to report a comparison of a single inhaler triple therapy with two dual therapies, providing much needed clinical evidence about the ability of a single inhaler triple therapy to reduce exacerbations. It is important to note that all treatments were comprised of different combinations of the same component molecules administered in the same Ellipta inhaler, in a single dose, once a day to allow direct treatment comparisons. We hope these results will inform global guidelines and look forward to sharing the results with regulatory authorities. We will continue to analyse the wealth of data generated to further the understanding of the treatment of COPD."

Mike Aguiar, CEO of Innoviva, Inc. commented: "The results of the IMPACT study have been long awaited by the medical community. We believe these data will significantly contribute to the body of evidence on the use of single inhaler triple therapy, as well as the ongoing role of ICS/LABA and LAMA/LABA treatments in appropriate patients with COPD."

Full results will be presented at upcoming scientific meetings and in peer-reviewed publications.

On 14 September 2017, GSK and Innoviva, Inc. announced that the EU Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending marketing authorisation for Trelegy Ellipta as a maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist.

On 18 September 2017, GSK and Innoviva, Inc. announced that the US Food and Drug Administration (FDA) approved Trelegy Ellipta for the long-term, once-daily, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, who are on a fixed-dose combination of fluticasone furoate and vilanterol for airflow obstruction and reducing exacerbations in whom additional treatment of airflow obstruction is desired or for patients who are already receiving umeclidinium and a fixed-dose combination of fluticasone furoate and vilanterol. Trelegy Ellipta is not indicated for relief of acute bronchospasm or the treatment of asthma.

Global regulatory filings with the IMPACT study are expected to commence in the second quarter of 2018 for consideration of expansion of the indicated patient population.

About IMPACT
The InforMing the PAthway of COPD Treatment (IMPACT) study was a randomised, double-blind, 3-arm parallel group, multicentre study evaluating FF/UMEC/VI (100mcg/62.5mcg/25mcg) versus FF/VI (100mcg/25mcg) and UMEC/VI (62.5mcg/25mcg), all given once daily via the Ellipta dry powder inhaler. The total duration of the study was approximately 55 weeks consisting of a 2-week run-in period, 52-week treatment period and a 1-week safety follow-up period. Patients had moderate to very severe symptomatic COPD with a history of exacerbation in the prior 12 months. In the study, 10,355 patients were treated in over 1,035 study centres globally.

The primary efficacy endpoint was the annual rate of on-treatment moderate and severe exacerbations. This was compared for FF/UMEC/VI versus FF/VI and, FF/UMEC/VI versus UMEC/VI. Other endpoints included lung function and patient reported outcomes, including health related quality of life measures.

About COPD
COPD is a disease of the lungs that includes chronic bronchitis, emphysema or both and limits airflow to the lungs, interfering with normal breathing. It is thought to affect 384 million people worldwide. 1 For people living with

COPD the inability to breathe normally and worsening of their symptoms can consume their daily life and make simple activities, like walking upstairs, an everyday struggle.

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. 2

Every person with COPD is different, with different needs, different challenges and different goals. Understanding this, and providing support to help meet these needs is the foundation of GSK's work.

About Trelegy Ellipta

Trelegy Ellipta is the first once-daily single inhaler triple therapy approved in the US for the long-term, once-daily, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, who are on a fixed-dose combination of fluticasone furoate and vilanterol for airflow obstruction and reducing exacerbations in whom additional treatment of airflow obstruction is desired or for patients who are already receiving umeclidinium and a fixed-dose combination of fluticasone furoate and vilanterol. Trelegy Ellipta is not indicated for relief of acute bronchospasm or the treatment of asthma.

Trelegy contains fluticasone furoate, an inhaled corticosteroid, umeclidinium, a long-acting muscarinic antagonist ; and vilanterol, a long-acting beta2-adrenergic agonist, in a single inhaler, the Ellipta.

Full US Prescribing Information, including BOXED WARNING and Medication Guide is available at: us.gsk.com .

Important Safety Information (ISI) for Trelegy Ellipta

The following ISI is based on the Highlights section of the US Prescribing Information for Trelegy Ellipta. Please consult the full Prescribing Information for all the labelled safety information for Trelegy Ellipta.

Long-acting beta2-adrenergic agonists (LABA), such as vilanterol, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths. This finding with salmeterol is considered a class effect of all LABA. The safety and efficacy of Trelegy Ellipta in patients with asthma have not been established. Trelegy Ellipta is not indicated for the treatment of asthma.

Trelegy Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins or any of the ingredients.

Trelegy Ellipta should not be initiated in patients experiencing episodes of acutely deteriorating COPD. Do not use

Trelegy Ellipta to treat acute symptoms.

Trelegy Ellipta should not be used in combination with other medicines containing LABA because of risk of overdose.

Candida albicans infection of the mouth and pharynx has occurred in patients treated with fluticasone furoate, a component of Trelegy Ellipta. Monitor patients periodically. Advise the patient to rinse his/her mouth with water without swallowing after inhalation to help reduce the risk.

There is an increased risk of pneumonia in patients with COPD taking Trelegy Ellipta . Monitor patients for signs and symptoms of pneumonia.

Patients who use corticosteroids are at risk for potential worsening of infections (e.g. existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex). Use Trelegy Ellipta with caution in patients with

these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients. There is a risk of impaired adrenal function when transferring from systemic corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to Trelegy Ellipta .

Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage of Trelegy Ellipta in susceptible individuals. If such changes occur, consider appropriate therapy.

If paradoxical bronchospasm occurs, discontinue Trelegy Ellipta and institute alternative therapy.

Use Trelegy Ellipta with caution in patients with cardiovascular disorders because of beta-adrenergic stimulation.

Assess patients for decrease in bone mineral density initially and periodically thereafter after prescribing Trelegy Ellipta .

Close monitoring for glaucoma and cataracts is warranted in patients taking Trelegy Ellipta . Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a healthcare provider immediately if symptoms occur.

Worsening of urinary retention may occur in patients taking Trelegy Ellipta . Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur.

Use Trelegy Ellipta with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis.

Be alert to hypokalemia and hyperglycemia in patients taking Trelegy Ellipta .

The most common adverse reactions reported for Trelegy Ellipta (incidence ≥1%) are headache, back pain, dysgeusia, diarrhea, cough, oropharyngeal pain, and gastroenteritis.

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 .

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®. 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.

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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 'Principal risks and uncertainties' in the company's Annual Report on Form 20-F for 2016.

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, including the development, regulatory and commercial plans for closed triple combination therapy and the potential benefits and mechanisms of action of closed triple combination therapy. 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. 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 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, 2016 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, which are on file with the U.S. 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. The information in this press release is provided only as of the date hereof, and 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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References

1. Global Initiative for Chronic Obstructive Lung Disease Global Initiative for Chronic Obstructive Lung Disease. 2017. Pocket guide to COPD diagnosis, management, and prevention. Available at: http://goldcopd.org/wp-content/uploads/2016/12/wms-GOLD-2017-Pocket-Guide.pdf
2. Diagnosis of COPD. World Health Organisation. Available at: http://www.who.int/respiratory/copd/diagnosis/en/
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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 20, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc