GLAXOSMITHKLINE PLC
Form 6-K
February 14, 2018

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 14 February 2018

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: 14 February 2018, London UK - LSE Announcement

GSK submits landmark IMPACT data to European Medicines Agency to support expanded label for Trelegy Ellipta

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced the submission of the landmark IMPACT data to the European Medicines Agency as part of a type II variation to support an expanded label for Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol, 'FF/UMEC/VI') in Europe for the maintenance treatment of moderate to severe chronic obstructive pulmonary disease (COPD) (for the relief of symptoms and reduction of exacerbations, see section 5.1).

Approval of the submission would mean FF/UMEC/VI, the only once-daily single inhalation triple therapy for the treatment of COPD, could be used by physicians to treat a wider population of patients with the condition who are at risk of an exacerbation and require triple therapy.

The regulatory submission is primarily based on data from the IMPACT study showing FF/UMEC/VI was superior to the inhaled corticosteroid/long-acting beta2-adrenergic agonist (ICS/LABA), Relvar/Breo (FF/VI), and long-acting muscarinic antagonist/long-acting beta2-adrenergic agonist (LAMA/LABA), Anoro (UMEC/VI), on a range of clinically important endpoints, including reducing the number of exacerbations or 'flare ups' patients experienced, and improving lung function and health related quality of life.

Dave Allen, Head, Respiratory Therapy Area, R&D, GSK said, "This filing is primarily based on the IMPACT study, which clarifies the type of patient most likely to benefit from once-daily single inhaler triple therapy, and adds to the evidence supporting the clinical profile of Trelegy Ellipta. The submission reflects our confidence in this medicine, which we believe has the potential to be an effective treatment option for appropriate patients with COPD who require triple therapy for symptom relief and exacerbation reduction."

FF/UMEC/VI was approved in Europe in November 2017 as a maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an ICS and a LABA.

The filing in Europe follows submission of a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) which is currently under review. Also included in the European submission are data showing FF/UMEC/VI was non-inferior to UMEC and FF/VI when used in combination in terms of improving lung function, quality of life and breathlessness, further adding to the evidence base (NCT02729051).

Dr. Theodore J. Witek Jr., Senior Vice President and Chief Scientific Officer of Innoviva added, "The data included in this submission build on existing evidence supporting the role of once-daily single inhaler triple therapy in the treatment of appropriate patients with COPD. If approved, updates to the Trelegy Ellipta labelling will give clinicians additional information to help guide their treatment choices."

About IMPACT
The landmark InforMing the PAthway of COPD Treatment (IMPACT) study evaluated the annual rate of on-treatment moderate/severe exacerbations for FF/UMEC/VI (100/62.5/25mcg) compared with FF/VI and UMEC/VI, two once-daily dual COPD therapies from GSK's existing portfolio. Headline results were announced in September 2017 and full data will be presented in peer-reviewed publications and future scientific meetings.

IMPACT is the first study to directly compare three commonly used COPD combination treatment classes delivered using the same dose and inhaler. The study enrolled 10,355 patients with COPD from 37 countries in over 1,035 study centres. Patients in the study had a history of exacerbation in the prior 12 months which is representative of over 45% of the global COPD patient population.1

About COPD
COPD is a progressive lung disease that is thought to affect around 384 million people worldwide.2 For people living with COPD, the inability to breathe normally can consume their daily lives and make simple activities, like walking up stairs, an everyday struggle.

Long-term exposure to inhaled 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.3

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 (FF/UMEC/VI)
FF/UMEC/VI is the first treatment to provide a combination of three molecules in a single inhaler that only needs to be taken as one inhalation, once a day. It contains fluticasone furoate, an inhaled corticosteroid, umeclidinium, a long-acting muscarinic antagonist; and vilanterol, a long-acting beta2-adrenergic agonist, delivered once-daily in GSK's Ellipta dry powder inhaler, which is used across the entire new portfolio of inhaled COPD medicines.

Substantial evidence from across multiple clinical programmes has demonstrated the benefit/risk of the molecules in FF/UMEC/VI both alone and in combination, for the treatment of COPD and it has been approved for use in appropriate patients with COPD in both the US and the EU.

FF/UMEC/VI was approved for use in Europe in November 2017 as as a maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist. The European Summary of Product Characteristics is available at: https://www.medicines.org.uk/emc/medicine/34357

FF/UMEC/VI was approved in the US in September 2017 for the long-term, once-daily, maintenance treatment of patients with COPD, including chronic bronchitis and/or emphysema, who are on a fixed-dose combination of FF/VI for airflow obstruction and reducing exacerbations in whom additional treatment of airflow obstruction is desired or for patients who are already receiving UMEC and a fixed-dose combination of FF/VI. Full US Prescribing Information, including BOXED WARNING and Medication Guide are available at: https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Trelegy/pdf/TRELEGY-PI

Regulatory applications for once-daily single inhaler triple therapy FF/UMEC/VI have been submitted and are undergoing assessment in a number of other countries.

GSK's commitment to respiratory disease
GSK has led the way in developing innovative medicines to advance the management of asthma and COPD for nearly 50 years. Over the last four years we have launched six innovative medicines responding to continued unmet patient need, despite existing therapies. This is an industry leading portfolio in breadth, depth and innovation, developed to reach the right patients, with the right treatment.

We remain at the cutting-edge of scientific research into respiratory medicine, working in collaboration with patients and the scientific community to offer innovative medicines aimed at helping to treat patients' symptoms and reduce the risk of their disease worsening. While respiratory diseases are clinically distinct, there are important

pathophysiological features that span them, and our ambition is to have the most comprehensive portfolio of medicines to address a diverse range of respiratory diseases. To achieve this, we are focusing on targeting the underlying disease-driving biological processes to develop medicines with applicability across multiple respiratory diseases. This approach requires extensive bioinformatics, data analytic capabilities, careful patient selection and stratification by phenotype in our clinical trials.

Important Safety Information for FF/UMEC/VI in the EU
The following Important Safety Information is based on a summary of the Summary of Product Characteristics for Trelegy Ellipta (FF/UMEC/VI). Please consult the full Summary of Product Characteristics for all the safety information.

FF/UMEC/VI is contraindicated in patients with hypersensitivity to either fluticasone furoate (FF), umeclidinium (UMEC), vilanterol (VI) or any of the excipients.

FF/UMEC/VI should not be used in patients with asthma since it has not been studied in this patient population. FF/UMEC/VI is not indicated for the treatment of acute episodes of bronchospasm.

In the event of deterioration of COPD during treatment with FF/UMEC/VI, a re-evaluation of the patient and of the COPD treatment regimen should be undertaken.

Administration of FF/UMEC/VI may produce paradoxical bronchospasm that may be life-threatening. Cardiovascular effects, such as cardiac arrhythmias e.g. atrial fibrillation and tachycardia, may be seen after the administration of muscarinic receptor antagonists and sympathomimetics, including FF/UMEC/VI. Therefore, FF/UMEC/VI should be used with caution in patients with unstable or life-threatening cardiovascular disease.

Systemic steroid effects may occur with any inhaled corticosteroid (ICS), particularly at high doses prescribed for long periods. These effects are much less likely to occur than with oral corticosteroids. Patients with moderate to severe hepatic impairment receiving FF/UMEC/VI should be monitored for systemic corticosteroid-related adverse reactions.

If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

FF/UMEC/VI should be used with caution in patients with convulsive disorders or thyrotoxicosis, in patients who are unusually responsive to beta2-adrenergic agonists and in patients with pulmonary tuberculosis or in patients with chronic or untreated infection.

Consistent with its antimuscarinic activity, FF/UMEC/VI should be used with caution in patients with urinary retention or with narrow-angle glaucoma.

An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving ICS. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies. There is no conclusive clinical evidence for intra-class differences in the magnitude of the pneumonia risk among ICS products.

Beta2-adrenergic agonists may produce significant hypokalaemia in some patients, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. No clinically relevant effects of hypokalaemia were observed in clinical studies with FF/UMEC/VI at the recommended therapeutic dose. Caution should be exercised when FF/UMEC/VI is used with other medicinal

products that also have the potential to cause hypokalaemia.

Beta2-adrenergic agonists may produce transient hyperglycemia in some patients. No clinically relevant effects on plasma glucose were observed in clinical studies with FF/UMEC/VI at the recommended therapeutic dose. Upon initiation of treatment with FF/UMEC/VI, plasma glucose should be monitored more closely in diabetic patients.

There have been reports of increases in blood glucose levels in diabetic patients treated with fluticasone furoate/umeclidinium/vilanterol and this should be considered when prescribing to patients with a history of diabetes mellitus.

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take FF/UMEC/VI.

The most frequently reported adverse reactions with FF/UMEC/VI were nasopharyngitis (7%), headache (5%) and upper respiratory tract infection (2%). Other common adverse reactions (reported with a frequency of ≥1/100 to <1/10) include: pneumonia, pharyngitis, rhinitis, influenza, cough, arthralgia and back pain.

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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Innoviva - Innoviva is focused on bringing compelling 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®, ANORO® ELLIPTA® and TRELEGY® 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 Trelegy Ellipta for COPD. For more information, please visit Innoviva's website at www.inva.com.

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Cautionary statement regarding forward-looking statementsGSK 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 September 30, 2017, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Innoviva's Annual Report on Form 10-K for the year ended December 31, 2017, to be filed with the SEC in the first quarter of 2018. 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).

Registered in England & Wales:
No. 3888792

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References (accessed January 2018)
1. GSK data on file. RF/CPD/0003/18. Frequency of acute exacerbations of COPD among patients treated with maintenance therapy in three observational studies.
2. 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
3. Diagnosis of COPD. World Health Organisation. Available at: http://www.who.int/respiratory/copd/diagnosis/en/

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: February 14, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc