GLAXOSMITHKLINE PLC
Form 6-K
September 21, 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 21 September 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: 21 September 2018, London UK - LSE Announcement

Trelegy Ellipta receives positive CHMP opinion supportingexpanded COPD indication in Europe

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion today supporting the use of Trelegy Ellipta (fluticasone furoate/umeclidinium/ vilanterol 'FF/UMEC/VI') in a broader group of patients with moderate to severe chronic obstructive pulmonary disease (COPD) and that labelling, if approved, will be updated to further reflect its effect on exacerbations of COPD.

The expanded indication for the once-daily single inhaler triple therapy would enable use by patients not adequately treated by a long-acting muscarinic receptor antagonist (LAMA) and long-acting b2-agonist (LABA). It would also reference the effect on exacerbations based on data from the InforMing the PAthway of COPD Treatment (IMPACT) study.

Dr. Hal Barron, Chief Scientific Officer and President, R&D, GSK, said, "Many patients with COPD continue to experience exacerbations despite taking dual bronchodilator therapies. The landmark IMPACT study provided compelling evidence on the role Trelegy Ellipta can play in reducing these debilitating events. If approved, the indication will recognise this and be expanded to enable more appropriate patients to access the first once-daily single inhaler triple therapy."

The CHMP's recommendation is based on a type II variation supported by data from the IMPACT study which showed Trelegy Ellipta was superior to the inhaled corticosteroid (ICS)/LABA Relvar/Breo Ellipta (FF/VI) and LAMA/LABA Anoro Ellipta (UMEC/VI) in patients with moderate to severe COPD on multiple clinically important endpoints, including reducing exacerbations and improving lung function and health related quality of life.

Dr Ted Witek, Senior Vice President and Chief Scientific Officer at Innoviva, added: "We welcome the CHMP's recognition of the evidence supporting use of once-daily single inhaler triple therapy in a broader group of appropriate patients with COPD and look forward to a decision from the European Commission in due course."

Trelegy Ellipta was originally approved in the European Union (EU) 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 (for effects on symptom control see section 5.1). The proposed new indication is 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 or a combination of a LABA and a LAMA (for effects on symptom control and prevention of exacerbations see section 5.1).

A CHMP positive opinion is one of the final steps before a final decision on the regulatory update is granted by the European Commission.

About IMPACT
The landmark 10,355-patient InforMing the PAthway of COPD Treatment (IMPACT) study is the first study to directly compare three commonly-used COPD combination treatment classes delivered using the same dose and inhaler. It is the second of two Phase III studies designed to investigate the efficacy and safety of FF/UMEC/VI in a single inhaler compared to other commonly-used COPD combination treatments.1

IMPACT evaluated as its primary endpoint the annual rate of on-treatment moderate/severe exacerbations for FF/UMEC/VI (100/62.5/25mcg) compared with its components, FF/VI (100/25mcg) and UMEC/VI (62.5/25mcg), two once-daily dual COPD therapies from GSK's existing portfolio. Results from IMPACT were recently published in

the New England Journal of Medicine.2

About Trelegy Ellipta (FF/UMEC/VI)
FF/UMEC/VI is the first COPD treatment to provide a combination of three molecules in a single inhaler that is taken in a single 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 in GSK's Ellipta dry powder inhaler, which is used across the entire new portfolio of inhaled COPD medicines.

Data from across multiple clinical programmes have demonstrated the benefit/risk of the molecules in FF/UMEC/VI 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 originally approved for use in the European Union 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 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 is approved in the US for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. It is not indicated for relief of acute bronchospasm or for the treatment of asthma. Full US Prescribing Information, including Patient Information is available at: https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Trelegy/pdf/TRELEGY-PI

FF/UMEC/VI has been approved in a number of other countries with further regulatory applications ongoing.

About COPD
COPD is a progressive lung disease that is thought to affect around 384 million people worldwide.3
For people living with COPD, the inability to breathe normally can consume their daily lives and make simple activities, like walking upstairs, an everyday struggle. Patients with COPD suffer from symptoms of breathlessness and many have a significant risk of exacerbations. Managing these aspects of the disease drives physician treatment choice.

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.4

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.

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 five 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 - a science-led global healthcare company with a special purpose: to help people do more, feel better, 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® and ANORO® ELLIPTA®. In addition, Innoviva retains a 15 percent economic interest in future payments made by GSK for TRELEGY® ELLIPTA® and earlier-stage programs partnered with Theravance Biopharma, Inc. 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 2017.

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, 2017, which is 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, to be filed with the SEC in the second 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)

References (accessed September 2018)

1. Lipson DA et al. FULFIL Trial: Once-Daily Triple Therapy for Patients with Chronic Obstructive Pulmonary Disease. Am J Resp Crit Care Med. 2017.
2. Lipson DA et al. Once-Daily Single Inhaler Triple Versus Dual Therapy in Patients with COPD. New England Journal of Medicine. 2018.
3. Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017. Available from: http://goldcopd.org.
4. Diagnosis of COPD. World Health Organization. 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 21, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc