GLAXOSMITHKLINE PLC
Form 6-K
May 29, 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 29 May 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: 29 May 2018, London UK - LSE Announcement

GSK submits regulatory application in Japan for once-daily single inhaler triple therapy FF/UMEC/VI for patients with COPD

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced the submission of a regulatory application to the Japanese Ministry of Health, Labour and Welfare (MHLW) for once-daily fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI 100/62.5/25 mcg) under the proposed brand name of Trelegy Ellipta for the treatment of adults with chronic obstructive pulmonary disease (COPD). This is the first regulatory filing to be made in Japan for a triple COPD therapy in a single inhaler.

Dave Allen, Head, Respiratory Therapy Area R&D, GSK said: "COPD is a debilitating lung disease affecting over five million people in Japan. Many patients require combination treatment with different types of medicines to reduce both symptoms and exacerbations but there is currently no triple therapy available in Japan delivered in a single inhaler. If approved, once-daily FF/UMEC/VI delivered in the Ellipta would be an important innovation in the management of COPD in Japan alongside our current range of treatments."1

The New Drug Application is primarily based on data from the Phase III IMPACT study which included 378 patients from Japan. In the overall study population, FF/UMEC/VI was superior to the inhaled corticosteroid/long-acting beta2-adrenergic agonist (ICS/LABA), Relvar/Breo Ellipta (FF/VI), and long-acting muscarinic antagonist/long-acting beta2-adrenergic agonist (LAMA/LABA), Anoro Ellipta (UMEC/VI), on multiple clinically important endpoints, including reducing exacerbations and improving lung function and health related quality of life. Similar trends were observed in the Japanese population for the primary endpoint as well as across multiple secondary and supportive efficacy endpoints.

Dr Ted Witek, Senior Vice President and Chief Scientific Officer at Innoviva added, "We are delighted to have filed a new drug application for the first single inhaler triple therapy for the treatment of COPD in Japan where the prevalence of COPD is of public concern. We look forward to a decision from the MHLW, which, if positive, would provide a new therapeutic option for appropriate patients with COPD in Japan."

The proposed indication is for the relief of various symptoms with COPD (chronic bronchitis, pulmonary emphysema) (in the case where concurrent use of inhaled corticosteroid, long-acting inhaled beta2-agonist and long-acting inhaled anticholinergic drug is required.)

FF/UMEC/VI is currently licensed for use in the US, EU and a number of other countries under the brand name Trelegy Ellipta. It contains three molecules, an ICS, a LAMA and a LABA, delivered in the Ellipta dry powder inhaler which is used across GSK's new portfolio of inhaled COPD medicines.

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.2

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 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.3

About 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 GSK's new portfolio of inhaled COPD medicines.

Data from across multiple clinical programmes have demonstrated the benefit of the molecules in FF/UMEC/VI, both alone and in combination, for the treatment of COPD.

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 is approved in Europe 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

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 worldwide.

About COPD
COPD is a progressive lung disease that is thought to affect around 384 million people worldwide.4
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.5

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 (ISI)
The following ISI is based on the Highlights section of the US Prescribing Information for FF/UMEC/VI. Please consult the full Prescribing Information for all the labelled safety information.

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

LABA monotherapy increases the risk of serious asthma-related events.

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 upper respiratory tract infection, pneumonia, bronchitis, oral candidiasis, headache, back pain, arthralgia, influenza, sinusitis, pharyngitis, rhinitis, dysgeusia, constipation, urinary tract infection, diarrhea, gastroenteritis, oropharyngeal pain, cough, and dysphonia.

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.

Trade marks are owned by or licensed to the GSK group of companies.

Innoviva - Innoviva is focused on on the management of royalty revenues from the respiratory inhalers RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA®, commercialized by Glaxo Group Limited (GSK). For more information, please visit Innoviva's website at www.inva.com.

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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 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 and Innoviva's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, both of 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. 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 April 2018)

1. Fukuchi Y et al. Prevalence of COPD in Japan: results from the NIPPON COPD epidemiology (NICE) study. Eur Respir J. 2001.
2. Lipson DA et al. FULFIL Trial: Once-Daily Triple Therapy for Patients with Chronic Obstructive Pulmonary Disease. Am J Resp Crit Care Med. 2017.
3. Lipson DA et al. Once-Daily Single Inhaler Triple Versus Dual Therapy in Patients with COPD. New England Journal of Medicine. 2018.
4. Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017. Available from: http://goldcopd.org.
5. 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: May 29, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc