GLAXOSMITHKLINE PLC
Form 6-K
November 01, 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 01 November 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

Wednesday 1 November 2017, London UK - LSE Announcement

GSK study demonstrates superiority of Anoro Ellipta to Stiolto Respimat in improving lung function in chronic obstructive pulmonary disease

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced positive data from a study comparing a once-daily long-acting muscarinic antagonist (LAMA) and a long-acting beta agonist (LABA) fixed-dose combination, Anoro Ellipta (umeclidinium/vilanterol 62.5mcg/25mcg; UMEC/VI) and Stiolto Respimat (tiotropium/olodaterol 5mcg/5mcg; TIO/OLO), for symptomatic patients with chronic obstructive pulmonary disease (COPD). These data have been published today in Advances in Therapy1 and are being presented today at the CHEST annual meeting of the American College of Chest Physicians in Toronto, Canada.

The primary endpoint for this eight-week, open-label, cross-over study of 236 patients with COPD was the demonstration of non-inferiority of UMEC/VI compared to TIO/OLO in improving lung function, as measured by trough FEV1 (Forced Expiratory Volume in 1 second) at week eight. This endpoint was met and, furthermore, UMEC/VI demonstrated superiority to TIO/OLO, with a difference in treatment effect of 52mL on trough FEV1 at week eight (UMEC/VI 180mL vs. TIO/OLO 128mL; 95% CI: 28, 77; $p<0.001$).

Both treatments demonstrated a comparable tolerability and safety profile with an overall incidence of on-treatment adverse events of 25% in the UMEC/VI group and 31% in the TIO/OLO group. The most frequently-reported adverse events were upper respiratory tract infections (UMEC/VI 8%; TIO/OLO 9%), cough (UMEC/VI 1%; TIO/OLO 1%) and diarrhoea (UMEC/VI 1%; TIO/OLO 1%).

Eric Dube, SVP, Head Global Respiratory, GSK said, "Improving lung function is a clear goal in patients with COPD.2 The challenge for healthcare professionals to date has been the lack of differentiation within the LAMA/LABA class. That is why we have conducted this study, as the first in-class head-to-head comparison of two fixed-dose once-daily LAMA/LABAs. These data demonstrate that UMEC/VI (Anoro) provides superior lung function improvements to the comparator TIO/OLO."

Michael Aguiar, CEO of Innoviva said, "COPD is a progressive, chronic disease, affecting over 300 million people worldwide. We believe that these data clearly demonstrate the benefit of Anoro Ellipta versus Stiolto Respimat for symptomatic moderate COPD patients whose primary therapeutic need is additional bronchodilatation and we are very pleased with these results."

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. 384 million people have COPD2 and it is estimated to become the 3rd leading cause of death worldwide by 2030.3 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 the Head-to-Head Study
The Anoro Ellipta (umeclidinium/vilanterol 62.5mcg/25mcg; UMEC/VI) versus Stiolto Respimat (tiotropium/olodaterol 5mcg/5mcg; TIO/OLO) head-to-head study is the first direct comparison of two fixed-dose once-daily LAMA/LABA combination therapies for COPD.

The study involved 236 adult symptomatic (MMRC >/= 2) patients with moderate COPD (post bronchodilator FEV1 ≤50 and ≥70% of predicted value), not receiving inhaled corticosteroid therapy at inclusion in the study, from 34 centres across Germany, Spain, UK and US. The primary objective of the study was to demonstrate that UMEC/VI was non-inferior to TIO/OLO in lung function at week eight, as measured by trough FEV1 (Forced Expiratory Volume in 1 second) with a non-inferiority margin of -50mL in the per protocol (PP) population. If non-inferiority was established, which was the case, superiority was then tested in the intent-to-treat (ITT) population.

The study was an 8-week, multicentre, randomised, open-label, two-period cross-over design. After an initial two week run-in period, eligible patients were randomised to receive UMEC/VI (62.5/25 mcg one inhalation once-daily) via the Ellipta inhaler followed by TIO/OLO 5/5 mcg (2 puffs of TIO/OLO 2.5/2.5 mcg once-daily) via the Respimat inhaler (each for 8 weeks with an interim 3-week washout), or vice versa. Treatments were administered open-label, since the inhalers were potentially identifiable, but spirometry was conducted in assessor-blind conditions.

Commitment to respiratory disease
GSK has been a leader in respiratory for over 45 years, developing new and first-in-class medicines, approaches and insights which have helped to influence and support the management of asthma and COPD. The company is relentless in striving to expand knowledge and the understanding of respiratory disease to help transform the way that medicines are developed. GSK is focused on identifying new scientific insights, applying our expertise and developing innovative new medicines that enable clinicians to tailor treatment to the individual needs of patients and help patients to live every breath.

About Anoro Ellipta
Anoro Ellipta (umeclidinium and vilanterol inhalation powder) is a combination of two bronchodilators in a single dry powder inhaler, the Ellipta. It contains umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta2 agonist (LABA). The dose of UMEC/VI is labelled as 55/22mcg in Europe (delivered dose) and 62.5/25mcg in the US (dispensed dose) and is delivered in the Ellipta inhaler.

Important Safety Information for Anoro Ellipta in the US
The following Important Safety Information (ISI) is based on the Highlights section of the Prescribing Information for Anoro Ellipta. Please consult the full Prescribing Information for all the labeled safety information for Anoro 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 Anoro in patients with asthma have not been established. Anoro is not indicated for the treatment of asthma.

Anoro is contraindicated in patients with severe hypersensitivity to milk proteins or any ingredients.

Anoro should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD, or as rescue therapy for the treatment of acute episodes of bronchospasm, which should be treated with an inhaled, short-acting beta2-agonist.

Anoro should not be used more often than recommended, at higher doses than recommended, or in conjunction with additional medicine containing a LABA, as an overdose may result.

Anoro should be used with caution when considering coadministration with long-term ketoconazole and other known strong cytochrome P450 3A4 inhibitors because increased cardiovascular adverse effects may occur.

Anoro can produce paradoxical bronchospasm, which may be life-threatening.

Anoro should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Anoro should be used with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

Anoro should be used with caution in patients with narrow-angle glaucoma. Instruct patients to contact a physician immediately should any signs or symptoms of narrow-angle glaucoma occur.

Anoro should be used with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder neck obstruction. Instruct patients to contact a physician immediately should any signs or symptoms of urinary retention occur.

Beta-adrenergic agonist medicines may produce significant hypokalemia and transient hyperglycemia in some patients.

The most common adverse reactions (incidence ≥1% and more common than placebo) with Anoro were pharyngitis, sinusitis, lower respiratory tract infection, constipation, diarrhea, pain in extremity, muscle spasms, neck pain, and chest pain.
Beta2-agonists, such as vilanterol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists on the cardiovascular system may be potentiated.

Use beta blockers with caution as they not only block the pulmonary effect of beta agonists, such as vilanterol, but may produce severe bronchospasm in patients with COPD.

Use with caution in patients taking non-potassium-sparing diuretics, as electrocardiographic changes and/or hypokalemia associated with non-potassium-sparing diuretics may worsen with concomitant beta-agonists.

Avoid co-administration of Anoro with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects such as cardiovascular effects, worsening of narrow-angle glaucoma, and worsening of urinary retention.

Full US prescribing information is available at: US Prescribing Information for Anoro Ellipta.

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.

ANORO®, and ELLIPTA® are trade marks of the GlaxoSmithKline group of companies. STIOLTO and RESPIMAT are trade marks of Boehringer Ingelheim.

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.

References
1. Feldman G et al. Advances in Therapy 2017; vol. 34: DOI 10.1007/s12325-017-0626-4
2. GOLD 2017 Global Strategy for the Diagnosis, Management and Prevention of COPD. Available from: http://goldcopd.org/gold-2017-global-strategy-diagnosis-management-prevention-copd/ [Last accessed: Oct. 2017]
3. World Health Organization. Chronic obstructive pulmonary disease. Available from: http://www.who.int/respiratory/copd/en/ [Last accessed: Oct. 2017]

GSK enquiries:

UK Media enquiries:	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Sarah Alspach	+1 202 715 1048	(Washington, DC)
	Sarah Spencer	+1 215 751 3335	(Philadelphia)
	Karen Hagens	+1 919 483 2863	(North Carolina)
Analyst/Investor enquiries:	Sarah Elton-Farr	+44 (0) 208 047 5194	(London)
	Tom Curry	+ 1 215 751 5419	(Philadelphia)
	Gary Davies	+44 (0) 20 8047 5503	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)

Innoviva, Inc. enquiries:

Investor Relations:	Eric d'Esparbes	+1 (650) 238-9605 investor.relations@inva.com	(Brisbane, Calif.)

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 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).

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

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: November 01, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc