GLAXOSMITHKLINE PLC
Form 6-K
December 21, 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 21 December 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: Thursday 21 December 2017, London UK - LSE Announcement

FDA approves US label update on ICS/LABA combinations in asthma, based on review of safety data

Boxed warning removed from ICS/LABA combination products, including BREO ELLIPTA, ADVAIR DISKUS and ADVAIR HFA

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced it has received approval by the US Food and Drug Administration (FDA) of labelling changes to remove the boxed warning from inhaled corticosteroid (ICS) / long-acting beta2 agonist (LABA) combination medicines, including BREO ELLIPTA (fluticasone furoate/vilanterol, FF/VI), ADVAIR DISKUS (fluticasone propionate/salmeterol, FSC) and ADVAIR HFA. The FDA also approved updates to the Warnings and Precautions section of labelling for the ICS/LABA class. These labelling updates were approved on December 20th 2017, after a review of safety data from 4 randomized controlled safety trials submitted by three companies, including GSK.

This decision follows a Post-Marketing Requirement, issued by the FDA in 2010, for manufacturers of LABA-containing medicines at that time indicated for the treatment of asthma, to each conduct a large-scale study on the safety of LABAs when used in combination with ICS in adults and adolescents with asthma. Each of the large-scale safety trials were
randomised, double-blind, 26-week, active-controlled clinical trials comparing the sponsor-specific ICS/LABAto the same dose of the ICS. As the manufacturer of FSC, the only ICS/LABA approved in children 4-11 years of age in the US at that time, GSK also conducted a separate, similarly-designed study in this age group.

GSK reported results from two safety studies that compared FSC, an ICS/LABA combination containing Fluticasone Propionate (FP) and salmeterol, to FP alone. The studies showed that there was no excess risk associated with salmeterol when used in combination with FP, when used to treat both adolescent and adult patients with asthma (AUSTRI, SAS115359), and children aged 4 - 11 years (VESTRI, SAS115358), as assessed by the composite endpoint of asthma-related events (death, intubations or hospitalisations).1,2 Both studies were completed ahead of the predefined FDA date of June 2017.

About the AUSTRI study (SAS115359)
The AUSTRI study is a global, multicentre, randomised stratified, double-blind, parallel-group active comparator, 26 week study in adolescents (12 - 17 years of age) and adults (18 years of age and older) whose asthma warrants treatment with controller asthma therapy. Patients were required to have a history of asthma for at least one year prior to randomisation and experienced a severe asthma exacerbation requiring treatment with oral corticosteroids (or their equivalent) or an asthma-related hospitalisation in the year prior to treatment, but not in the 30 days prior to randomisation.

Patients were randomised to either FSC or FP. The FP (ICS) treatment dose (100mcg, 250mcg or 500mcg) was determined by the previous use of controller medications and an assessment of the patient's asthma control. Upon entry into the study, patients took part in a screening period of up to two weeks, a randomisation visit (visit 2) followed by a treatment period of 26 weeks where patients attended 3 on-treatment clinic visits. Months where there was not a visit, patients were contacted by telephone. Serious adverse events were collected within six months after the first use of study drug or seven days after the last date of study drug treatment, whichever date was greater. Patients were permitted to use albuterol/salbutamol rescue medication throughout the study.

The primary analysis was to determine whether the addition of LABA to ICS therapy (FSC) is non-inferior to ICS therapy alone (FP) on risk of a composite of serious asthma events (asthma-related hospitalisation, intubation and death). To demonstrate non-inferiority, a predefined margin of 2 was required, meaning the upper limit of the 95% confidence interval needed to be less than two to rule out a doubling in the risk of incidence on FSC compared with FP. All serious asthma related events were adjudicated by an independent committee.

The full results for this study are posted on the GSK Clinical Study Register and were published in the New England Journal of Medicine (NEJM).1

About the VESTRI study (SAS115358)
The VESTRI study is a global, multicentre, randomised stratified, double-blind, parallel-group active comparator, six-month study in paediatric patients (4 - 11 years of age) with asthma. Patients were required to have a history of persistent asthma and a history of an asthma exacerbation in the year prior to study randomisation. Eligibility for participation into the study was based on a review of pre-study asthma medications, assessment of asthma control, based on the Childhood-Asthma Control Test2 and a history of an asthma exacerbation requiring a systemic corticosteroid in the previous year.
Patients were screened at visit one to assess eligibility and subsequently randomised 1:1 to either FSC (100/50 mcg, 250/50 mcg) or FP (100mcg, 250 mcg) at visit two. Patients returned to the clinic after two weeks (visit three) and then at two-monthly intervals up to the final end of treatment clinic visit at six months. Patients' status in the months where there was not a visit was assessed by telephone contact. A follow-up phone call to query serious adverse events was made approximately one-week after end of treatment for both patients completing 6-month study treatment and those who ended study treatment prematurely. Patients were permitted to use albuterol/salbutamol rescue medication throughout the study. FSC 250/50 mcg and FP 250 mcg are not currently indicated in children 4 - 11 years of age according to US-approved product information.

The primary analysis was to determine whether the addition of LABA to ICS therapy (FSC) is non-inferior to ICS therapy alone (FP) in terms of the risk of a composite of serious asthma-related events (asthma-related hospitalisation, intubation and death). To demonstrate non-inferiority, a predefined margin of 2.675 was required, meaning the upper limit of the 95% confidence interval needed to be less than 2.675 to rule out an increase in the risk of a serious asthma related event on FSC compared with FP. All serious asthma related events were adjudicated by an independent committee.

The full results for this study are posted on the GSK Clinical Study Register and were published in the New England Journal of Medicine (NEJM).2

About asthma
Asthma is a chronic lung disease that inflames and narrows the airways. Asthma affects 358 million people worldwide . Despite medical advances, more than half of patients continue to experience poor control and significant symptoms impacting their daily life.

The causes of asthma are not completely understood but likely involve an interaction between a person's genetic make-up and the environment. Key risk factors are inhaled substances that provoke allergic reactions or irritate the airways.

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.

About Advair/Seretide (US Indication)

ADVAIR DISKUS is indicated for the twice-daily treatment of asthma in patients aged 4 years and older.
ADVAIR HFA is indicated for the twice-daily treatment of asthma in patients aged 12 years and older.
ADVAIR should be used for patients not adequately controlled on a long-term asthma control medication such as an ICS or whose disease warrants initiation of treatment with an ICS/LABA (inhaled corticosteroid/long- acting beta2-adrenergic agonist).
ADVAIR is NOT indicated for the relief of acute bronchospasm.

Important Safety Information for ADVAIR

CONTRAINDICATIONS

ADVAIR is contraindicated for primary treatment of status asthmaticus or other acute episodes of asthma or chronic obstructive pulmonary disease (COPD) where intensive measures are required.

ADVAIR DISKUS is contraindicated in patients with severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone propionate, salmeterol, or any of the excipients. ADVAIR HFA is contraindicated in patients with hypersensitivity to any of the ingredients.

WARNINGS AND PRECAUTIONS

LABA monotherapy increases the risk of asthma-related death and the risk of asthma-related hospitalizations in pediatric and adolescent patients. These findings are considered a class effect of LABA monotherapy. When LABA are used in fixed-dose combination with ICS, data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone.

ADVAIR should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of asthma or COPD.

ADVAIR should not be used for the relief of acute symptoms, ie, as rescue therapy for the treatment of acute episodes of bronchospasm. An inhaled, short-acting beta2-agonist, not ADVAIR, should be used to relieve acute symptoms such as shortness of breath.

ADVAIR should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using ADVAIR should not use another medicine containing a LABA (eg, salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol, vilanterol) for any reason.

Oropharyngeal candidiasis has occurred in patients treated with ADVAIR. Advise patients to rinse the mouth with water without swallowing following inhalation to help reduce the risk of oropharyngeal candidiasis.

Patients who use corticosteroids are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients. Use caution in patients with the above because of the potential for worsening of these infections.

Particular care is needed for patients who have been transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after

transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. Slowly taper the dose of systemic corticosteroids if transferring patients to ADVAIR.

Hypercorticism and adrenal suppression may occur with high doses of inhaled corticosteroids, including fluticasone propionate, or at the recommended dose in susceptible individuals. If such effects occur, discontinue ADVAIR slowly.

The use of strong cytochrome P450 3A4 (CYP3A4) inhibitors (eg, ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, telithromycin) with ADVAIR is not recommended because increased systemic corticosteroid and increased cardiovascular adverse effects may occur.

If paradoxical bronchospasm occurs, discontinue ADVAIR immediately and institute alternative therapy.

Salmeterol, a component of ADVAIR, can produce a clinically significant cardiovascular effect in some patients as measured by pulse rate, blood pressure, and/or symptoms. If such effects occur, ADVAIR may need to be discontinued. ADVAIR should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, advanced age, poor nutrition, or chronic use of drugs that can reduce bone mass (eg, anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care.

Inhaled corticosteroids, as well as poorly controlled asthma, may cause a reduction in growth velocity, and the long-term effect on final adult height is unknown. Patients should be maintained on the lowest dose of inhaled corticosteroid that effectively controls their asthma. Monitor growth of pediatric patients.

Glaucoma, increased intraocular pressure, and cataracts have been reported in patients with asthma and COPD following the long

term administration of inhaled corticosteroids, including fluticasone propionate, a component of ADVAIR. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

Be alert to hypokalemia, hyperglycemia, and systemic eosinophilic conditions, such as Churg-Strauss syndrome.

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

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥3%) in subjects with asthma taking ADVAIR DISKUS 100/50, ADVAIR DISKUS 250/50, and placebo, respectively, were upper respiratory tract infection (27%, 21%, 14%), pharyngitis (13%, 10%, 6%), upper respiratory inflammation (7%, 6%, 5%), sinusitis (4%, 5%, 4%), hoarseness/dysphonia (5%, 2%, <1%), oral candidiasis (1%, 4%, 0%), viral respiratory infections (4%, 4%, 3%), bronchitis (2%, 8%, 2%), cough (3%, 6%, 2%), headaches (12%, 13%, 7%), nausea and vomiting (4%, 6%, 1%), gastrointestinal discomfort and pain (4%, 1%, 1%), diarrhea (4%, 2%, 1%), viral gastrointestinal infections (3%, 0%, 2%), candidiasis unspecified site (3%, 0%, 1%), and musculoskeletal pain (4%, 2%, 3%). The types of adverse reactions and events reported were similar in subjects treated with ADVAIR DISKUS 500/50.

Most common adverse reactions (incidence ≥3%) in subjects with asthma taking ADVAIR HFA 45/21, ADVAIR HFA 115/21, and placebo, respectively, were upper respiratory tract infection (16%, 24%, 13%), throat irritation (9%, 7%, 7%), upper respiratory inflammation (4%, 4%, 3%), hoarseness/dysphonia (3%, 1%, 0%), viral respiratory infections (3%, 5%, 4%), headaches (21%, 15%, 11%), dizziness (4%, 1%, 0%), nausea and vomiting (5%, 3%, 3%), viral gastrointestinal infections (4%, 2%, 2%), gastrointestinal signs and symptoms (3%, 2%, 1%), musculoskeletal pain (5%, 7%, 4%), and muscle pain (4%, 1%, <1%). The incidence of common adverse reactions reported was similar in subjects treated with ADVAIR HFA 230/21.

DRUG INTERACTIONS

The use of strong cytochrome P450 3A4 (CYP3A4) inhibitors (eg, ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, telithromycin) with ADVAIR is not recommended

because increased systemic corticosteroid and increased cardiovascular adverse effects may occur.

ADVAIR should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, because the action of salmeterol, a component of ADVAIR, on the vascular system may be potentiated by these agents.

Use beta-blockers with caution as they not only block the pulmonary effect of beta

agonists, such as salmeterol, a component of ADVAIR, but may also produce severe bronchospasm in patients with asthma or COPD.

Use ADVAIR with caution in patients taking non-potassium-sparing diuretics (such as loop or thiazide diuretics), as electrocardiographic changes and/or hypokalemia associated with non-potassium-sparing diuretics may worsen with coadministration with beta-agonists, such as salmeterol.

USE IN SPECIFIC POPULATIONS

Fluticasone propionate and salmeterol are predominantly cleared by hepatic metabolism. Impairment of liver function may lead to accumulation of fluticasone propionate and salmeterol in plasma. Therefore, patients with hepatic disease should be closely monitored.

Full US Prescribing Information, including Medication Guide will be available soon at: us.gsk.com . Prior to the updated label being posted online, a copy of the label may be requested from one of the GSK Media or Investor Relations contacts listed in the "GSK Enquiries" section at the end of this document.

Seretide Accuhaler is indicated in Europe in the regular treatment of patients aged 4 and over with asthma, where use of a combination product (long-acting ß2-agonist, LABA, and inhaled corticosteroid, ICS) is appropriate: Patients not adequately controlled on both ICS and 'as-needed' short-acting ß2-agonist (SABA); Patients already adequately controlled on both ICS and LABA.

For the UK Summary of Product Characteristics (SmPC), please visit:
https://www.medicines.org.uk/emc/medicine/2317/SPC/Seretide+100,+250,+500+Accuhaler

About BREO ELLIPTA

In the US BREO ELLIPTA is indicated for the once-daily treatment of asthma in patients aged 18 years and older uncontrolled on an inhaled corticosteroid (ICS) or whose disease warrants an ICS and long-acting beta2-adrenergic agonist (LABA).

BREO is NOT indicated for the relief of acute bronchospasm.

Safety Information for BREO Ellipta*

CONTRAINDICATIONS

BREO is contraindicated for primary treatment of status asthmaticus or other acute episodes of chronic obstructive pulmonary disease (COPD) or asthma where intensive measures are required.

BREO is contraindicated in patients with severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone furoate, vilanterol, or any of the excipients.

WARNINGS AND PRECAUTIONS

LABA monotherapy increases the risk of asthma-related death and the risk of asthma-related hospitalizations in pediatric and adolescent patients. These findings are considered a class effect of LABA monotherapy. When LABA

are used in fixed-dose combination with ICS, data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone.

BREO should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD or asthma.

BREO is not a rescue medication and should not be used for the relief of acute bronchospasm or symptoms.

BREO should not be used more often or at higher doses than recommended, or with another LABA (eg, salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs, like LABA.

Oropharyngeal candidiasis has occurred in patients treated with BREO. Advise patients to rinse the mouth with water without swallowing after inhalation.

Use caution in patients who use corticosteroids as they are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients.

Particular care is needed for patients transferred from systemic corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer. Taper patients slowly from systemic corticosteroids if transferring to BREO.

Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage of inhaled corticosteroids in susceptible individuals. If such changes occur, discontinue BREO slowly.

Caution should be exercised when considering the coadministration of BREO with long-term ketoconazole and other known strong CYP3A4 inhibitors (eg, ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased systemic corticosteroid and cardiovascular adverse effects may occur.

If paradoxical bronchospasm occurs, discontinue BREO immediately and institute alternative therapy.

Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of BREO. Discontinue BREO if such reactions occur.

Vilanterol can produce clinically significant cardiovascular effects in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, and also cardiac arrhythmias, such as supraventricular tachycardia and extrasystoles. If such effects occur, BREO may need to be discontinued. BREO should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Decreases in bone mineral density have been observed with long

term administration of products containing inhaled corticosteroids. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, advanced age, poor nutrition, or chronic use of drugs that can reduce bone mass (eg, anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care.

Glaucoma, increased intraocular pressure, and cataracts have been reported in patients with COPD or asthma following the long-term administration of inhaled corticosteroids. Close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

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

Be alert to hypokalemia and hyperglycemia.

Orally inhaled corticosteroids may reduce growth velocity in children and adolescents.

ADVERSE REACTIONS

In a 12-week trial, adverse reactions (≥2% incidence and more common than placebo) reported in subjects taking BREO 100/25 (and placebo) were: nasopharyngitis, 10% (7%); headache, 5% (4%); oropharyngeal pain, 2% (1%); oral candidiasis, 2% (0%); and dysphonia, 2% (0%). In a separate 12-week trial, adverse reactions (≥2% incidence) reported in subjects taking BREO 200/25 (or BREO 100/25) were: headache, 8% (8%); nasopharyngitis, 7% (6%); influenza, 3% (3%); upper respiratory tract infection, 2% (2%); oropharyngeal pain, 2% (2%); sinusitis, 2% (1%); bronchitis, 2% (<1%); and cough, 1% (2%).

Additional adverse reactions (≥2% incidence) reported in subjects taking BREO 200/25 in a 24-week trial included viral respiratory tract infection, pharyngitis, pyrexia, and arthralgia; and with BREO 100/25 or 200/25 in a 12-month trial included pyrexia, back pain, extrasystoles, upper abdominal pain, respiratory tract infection, allergic rhinitis, pharyngitis, rhinitis, arthralgia, supraventricular extrasystoles, ventricular extrasystoles, acute sinusitis, and pneumonia.

In a 24- to 76-week trial of subjects with ≥1 asthma exacerbations in the past year, asthma-related hospitalizations occurred in 1% of subjects taking BREO 100/25. No asthma-related deaths or intubations were observed.

DRUG INTERACTIONS

Caution should be exercised when considering the coadministration of BREO with long

term ketoconazole and other known strong CYP3A4 inhibitors. See prior Warning and Precaution regarding CYP3A4 inhibitors.

BREO 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 they may potentiate the effect of vilanterol on the cardiovascular system.

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 or asthma.

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

USE IN SPECIFIC POPULATIONS

BREO is not indicated for children and adolescents; the safety and efficacy in patients aged ≤17 years have not been established.

Use BREO with caution in patients with moderate or severe hepatic impairment. Fluticasone furoate systemic exposure increased by up to 3-fold in subjects with hepatic impairment. Monitor for corticosteroid-related side effects.

Full US Prescribing Information, including Medication Guide will be available soon at: us.gsk.com . Prior to the updated label being posted online, a copy of the label may be requested from one of the GSK Media or Investor Relations contacts listed in the "GSK Enquiries" section at the end of this document.

BREO ELLIPTA is known as RELVAR ELLIPTA in Europe where it is indicated for the regular treatment of patients aged 12 and over with asthma, where use of a combination product (long-acting beta2-agonist, LABA, and inhaled corticosteroid, ICS) is appropriate: Patients not adequately controlled on both ICS and 'as-needed' short-acting beta2- agonist (SABA).
Full EU prescribing information is available at: EU Prescribing Information for Relvar Ellipta.

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.

References

1. Stempel D, et al. N Engl J Med. 2016;374:1822-1830.
2. David A, et al. N Engl J Med. 2016;375(9):840-9.

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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 2016.

Registered in England & Wales:

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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: December 21, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc