GLAXOSMITHKLINE PLC
Form 6-K
March 05, 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 05 March 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 5th March 2018, London UK - LSE Announcement

Nucala (mepolizumab) improved asthma control in patients uncontrolled on Xolair (omalizumab)

Positive clinical study outcomes observed for severe eosinophilic asthma patients uncontrolled on omalizumab when switched to mepolizumab in an open-label single arm study

GlaxoSmithKline plc (LSE/NYSE: GSK) today presented positive results from the OSMO study at the American Academy of Allergy, Asthma & Immunology (AAAAI) and World Allergy Organization (WAO) Joint Congress in Orlando. The results showed that severe asthma patients who are uncontrolled despite receiving Xolair (omalizumab) and who are eligible for treatment with Nucala (mepolizumab), experience improved asthma control when switched on to mepolizumab.

OSMO is an open-label, single-arm study which investigated whether patients who had been receiving omalizumab, (a biologic targeting IgE in patients with allergic sensitisation) for an average of 2.5 years and continued to have uncontrolled severe asthma, gained better asthma control following a switch to mepolizumab, (a biologic targeting IL-5 for patients with severe eosinophilic asthma). In the study 145 patients, who were documented to have experienced at least two asthma exacerbations in the year prior to enrolment, were switched directly to mepolizumab without a wash-out period and followed for 32 weeks. In this study, mepolizumab data compared with baseline values prior to first dose, unless otherwise stated:

Met the primary endpoint of asthma control with clinically significant improvements, as evaluated by the Asthma Control Questionnaire (ACQ-5), with a mean change from baseline of -1.45 at week 32

Met all secondary endpoints and other key endpoints:

- Rate of exacerbations requiring oral steroids reduced by 64% vs prior 12 months (3.26 to 1.18)
- Rate of exacerbations requiring an ED visit or hospitalization reduced by 69% vs prior 12 months (0.63 to 0.19)
- Improvement in lung function (pre-bronchodilator FEV1) of 159 mL vs baseline
- Improvement in Quality of life as evaluated by the SGRQ (-19 units, compared with MCID -4.0) vs baseline
- Reduction in blood eosinophils of approximately 80% by Week 4 (vs baseline), which was sustained until Week 32
- Safety profile was consistent with the known profile of the treatment

Ken Chapman, Professor of Medicine, University of Toronto and an investigator in the OSMO study said: "Patients participating in this study suffered burdensome day to day asthma symptoms and frequently required access to urgent care when their asthma symptoms significantly worsened. Like many similar patients, they had both eosinophilic and allergic characteristics, making them eligible to receive treatment with either omalizumab or mepolizumab. OSMO showed us that when these patients remained uncontrolled on omalizumab and were then switched to mepolizumab, they experienced significant improvements - fewer symptoms, better lung function, improved asthma-related quality of life and fewer exacerbations. This study is a valuable addition to our understanding of how to manage patients with biologic therapies."

In a further abstract/poster presented at AAAAI/WAO Joint Congress, a pooled, post-hoc meta-analysis of data from the MENSA and MUSCA studies, mepolizumab showed improvements in lung function of patients with severe eosinophilic asthma, measured by morning peak expiratory flow (AM PEF), compared with placebo. Early improvements were seen in week one and sustained at the end of the observational period: the mean change in AM PEF at week one was 10 L/min in the mepolizumab group compared with 2L/min in the placebo group and at the end of the observational period the mean change in AM PEF was 26 L/min in the mepolizumab group compared to 4 L/min in the placebo group. This improvement was shown to be greater at higher eosinophil counts.

Jonathan Sweeting, SVP and Head, Global Respiratory Franchise, GSK said: "It is important to have evidence to support decisions on prescribing the right treatment to the right severe asthma patient. There is existing data that supports the use of mepolizumab in patients with severe eosinophilic asthma; with OSMO we wanted to understand how to manage the more complex patients who are eligible to be treated with omalizumab or mepolizumab. The results presented today provide evidence that supports the use of mepolizumab in those eligible patients who are not well controlled by omalizumab. In addition, the meta-analysis we are presenting, which showed Nucala provides an early improvement, sustained over time in lung function compared with placebo, is further evidence supporting the effectiveness of this treatment in patients with severe eosinophilic asthma."

About the OSMO study
OSMO was an international, open-label, single arm trial. It enrolled patients aged 12 and older with severe eosinophilic asthma who were receiving omalizumab, but were not optimally controlled, based on Asthma Control Questionnaire score of >1.5 at screening and baseline and who experienced > 2 exacerbations in the past 12 months. The Asthma Control Questionnaire (ACQ-5) is a validated, self-administered tool, used by physicians to assess asthma control and changes in asthma control. Patients also required a peripheral eosinophil blood count of ≥150 cells/μL at study start or ≥300 cells/μL in the past 12 months to be eligible for mepolizumab.

About the meta-analysis
A post-hoc meta-analysis of data from two randomised, double-blind, placebo-controlled studies (MENSA and MUSCA) of 4-weekly sub-cutaneous mepolizumab 100 mg (n=454) versus placebo (n=456) in patients with severe eosinophilic asthma. All patients received high dose ICS plus ≥1 controller medication, had ≥2 exacerbations in the previous year and blood eosinophils ≥150 cells/μL at screening or ≥300 cells/μL in the previous year. The analysis assessed the effect of mepolizumab on AM PEF based on study entry criteria and by eosinophil thresholds. Data were analysed using a mixed model repeated measures controlling for multiple covariates.

About Nucala (mepolizumab)
NUCALA is a market leading biologic treatment for patients with severe asthma whose symptoms are driven by inflammation linked to higher-than-normal eosinophils (a type of white blood cell) being present in the blood. When present in the body in normal levels, eosinophils can play a role in protecting the body against infection but over-production can cause inflammation in vital organs and tissues, sometimes permanently damaging them.

When inflammation occurs in the lungs it can affect the airways, making breathing difficult and increasing the frequency of exacerbations or asthma attacks. Although the mechanism of action has not been definitively established, Nucala is believed to work by preventing the 'IL-5' cytokine from binding to its receptor on the surface of eosinophil cells, which in turn reduces eosinophil levels. The clinical trial programme to date has shown that Nucala consistently reduced exacerbations, improved patient's quality of life and maintains long term reduction of oral steroid dose.

Mepolizumab has been studied in over 3,000 patients in 16 clinical trials across a number of eosinophilic conditions, and is currently being investigated for severe hypereosinophilic syndrome and nasal polyposis.

Nucala 100mg is approved for the use as an add-on treatment of patients with severe eosinophilic asthma in over 40 countries including the EU, US, and Japan and has been prescribed to over 18,000 patients in the US. Mepolizumab 300mg is now approved in the US for the treatment of adult patients with a rare disease called eosinophilic granulomatosis with polyangiitis (EGPA). An sBLA has also been filed for the treatment in patients with chronic obstructive pulmonary disease (COPD).

Nucala is a trade mark of the GSK group of companies.

In the US, Nucala (100mg fixed dose subcutaneous injection of mepolizumab) is licensed as an add-on maintenance treatment for patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Nucala (3x

100mg subcutaneous injection of mepolizumab) is licensed for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). Nucala is not approved for the relief of acute bronchospasm or status asthmaticus. Full US Prescribing Information is available at US Prescribing Information Nucala.

In the EU, Nucala (100mg fixed dose subcutaneous injection of mepolizumab) is licensed as an add-on treatment for severe refractory eosinophilic asthma in adult patients. For the EU Summary of Product Characteristics for Nucala, please visit:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003860/WC500198037.pdf

GSK's commitment to respiratory disease
GSK has been developing new and first-in-class medicines, approaches and insights, which have been leading scientific understanding of the management of asthma and COPD for nearly 50 years. With the broadest portfolio of treatments for people with asthma and COPD, launched in the last four years, providing five new inhaled treatments in a single inhaler device and a market-leading biologic, our medicines are reaching the right patients, with the right treatments, every day.

GSK is relentless in striving to expand knowledge and understanding of respiratory diseases to help address unmet need and transform the way that medicines are developed. The company is focused on applying our expertise to identify new scientific insights and discover innovative new medicines in the disease areas of COPD, where we are targeting fundamental drivers of disease; asthma and severe asthma, to move from secondary prevention to primary disease modification; and idiopathic pulmonary fibrosis and acute lung injury where there is significant unmet need for new treatments; to enable clinicians to treat the individual needs of patients, to help patients to live every breath.

Important Safety Information for Nucala
The following information is based on the US Prescribing Information for Nucala. Please consult the full Prescribing Information for all the labelled safety information for Nucala.

CONTRAINDICATIONS
Nucala should not be administered to patients with a history of hypersensitivity to mepolizumab or excipients in the formulation.

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions
Hypersensitivity reactions (e.g. anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred following administration of Nucala. These reactions generally occur within hours of administration but in some instances can have a delayed onset (i.e. days). In the event of a hypersensitivity reaction, Nucala should be discontinued.

Acute Asthma Symptoms or Deteriorating Disease
Nucala should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

Opportunistic Infections: Herpes Zoster
In controlled clinical trials, 2 serious adverse reactions of herpes zoster occurred in subjects treated with Nucala compared to none in placebo. Consider varicella vaccination if medically appropriate prior to starting therapy with Nucala.

Reduction of Corticosteroid Dosage
Do not discontinue systemic or inhaled corticosteroids (ICS) abruptly upon initiation of therapy with Nucala. Decreases in corticosteroid doses, if appropriate, should be gradual and under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection
It is unknown if Nucala will influence a patient's response against parasites. Treat patients with pre-existing helminth infections before initiating therapy with Nucala. If patients become infected while receiving treatment with Nucala and do not respond to anti-helminth treatment, discontinue treatment with Nucala until infection resolves.

ADVERSE REACTIONS
The most common adverse reactions (≥3% and more common than placebo) reported in the first 24 weeks of two clinical trials with Nucala (and placebo) were: headache, 19% (18%); injection site reaction, 8% (3%); back pain, 5% (4%); fatigue, 5% (4%); influenza, 3% (2%); urinary tract infection 3% (2%); abdominal pain upper, 3% (2%); pruritus, 3% (2%); eczema, 3% (<1%); and muscle spasm, 3% (<1%).

Systemic Reactions, including Hypersensitivity Reactions: In 3 clinical trials, 3% of subjects who received Nucala experienced systemic (allergic and nonallergic) reactions compared to 5% in the placebo group. Systemic allergic/hypersensitivity reactions were reported by 1% of subjects who received Nucala compared to 2% of subjects in the placebo group. Manifestations included rash, pruritus, headache, and myalgia. Systemic nonallergic reactions were reported by 2% of subjects who received Nucala and 3% of subjects in the placebo group. Manifestations included rash, flushing, and myalgia. A majority of the systemic reactions were experienced on the day of dosing. Reports of anaphylaxis have been received postmarketing.

Injection site reactions (e.g. pain, erythema, swelling, itching, burning sensation) occurred at a rate of 8% in subjects treated with Nucala compared with 3% in subjects treated with placebo.

USE IN SPECIFIC POPULATIONS
The data on pregnancy exposures from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as mepolizumab, are progressively transported across the placenta in a linear fashion as pregnancy progresses; therefore, potential effects on a foetus are likely to be greater during the second and third trimesters of pregnancy.

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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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.

Registered in England & Wales:
No. 3888792

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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: March 05, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc