GLAXOSMITHKLINE PLC
Form 6-K
March 06, 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 06 March 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: Monday 6 March, 2017, London UK - LSE Announcement

GSK's MUSCA study shows Nucala® (mepolizumab) significantly improves quality of life and lung function in severe asthma patients with an eosinophilic phenotype

GlaxoSmithKline plc (LSE/NYSE:GSK) today announced data demonstrating that severe asthma patients, whose disease is driven by eosinophilic inflammation, treated with first-in-class biologic Nucala® (mepolizumab) added-on to standard of care, achieved clinically and statistically significant improvements in their health-related quality of life and lung function, when compared to patients treated with placebo and standard of care. These results are from the phase IIIb MUSCA study (NCT02281318, 200862), which successfully met all its primary and secondary endpoints.

Results of the study, presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting, showed in patients treated with mepolizumab as an add on to standard care:

St. Georges Respiratory Questionnaire (SGRQ) score (primary endpoint), a measure of quality of life, improved by 7.7 units from baseline vs. placebo (p=0.001) after 24 weeks - nearly double the defined clinically meaningful difference of ≥4.0 units.

Lung function (first secondary endpoint), as measured by pre-bronchodilator FEV1, increased by 120mL (p=0.001) more than in placebo patients at week 24 - a clinically relevant and statistically significant improvement.

FEV1 and SGRQ scores were also measured during the study, with improvements seen at the first measurement interval, after the first four weeks and sustained throughout the 24-week trial.

Asthma control, as measured by the Asthma Control Questionnaire-5 (ACQ-5) (additional secondary endpoint), showed a significant improvement vs. placebo in the mepolizumab treatment group by 0.40 units (p<0.001).

SGRQ score is an important patient-reported outcome measure used to understand how severe asthma affects a patient's quality of life. It looks at symptoms, activity levels and the impact asthma is having on people with the disease from a physiological and social perspective. MUSCA is the first mepolizumab clinical trial to specifically look at health-related quality of life as a primary endpoint and assess SGRQ score on multiple occasions throughout the study. FEV1 is a measure of how much air a person can forcefully blow out of their lungs and is used to assess how a patient's breathing is improving. In the clinical development program, mepolizumab did not provide consistent improvements in mean change from baseline in FEV1.

Dr Frank Albers, Medical Affairs Lead for Nucala, GSK said: "The data from the MUSCA study underscore the importance of Nucala as a treatment option for patients with severe asthma with an eosinophilic phenotype. These are patients who have very limited treatment options to control their asthma. For them shortness of breath, wheezing, coughing and the risk of an asthma attack is an ever present occurrence and one that can have a severe impact their life on a daily basis. By demonstrating improvements in a range of important markers of asthma control, including quality of life and lung function, these data reinforce the valuable role Nucala can play in the treatment of some of the most severe asthma patients."

Exploratory endpoints were the annual rate of exacerbations (asthma attacks), which was reduced by 58%, and the number of exacerbations requiring emergency room visits or hospitalisation, which was reduced by 68% for people treated with mepolizumab compared with placebo. These results were comparable to those seen in the pivotal phase III MENSA study. Safety was also assessed and the safety profile of mepolizumab in the MUSCA study was consistent with the product label for Nucala.

About the MUSCA study (200862) - Poster no. L17 and L18
The MUSCA study (Mepolizumab adjUnctive therapy in subjects with Severe eosinophiliC Asthma) involved 551 patients treated with Nucala 100mg subcutaneous injection, every 4 weeks for a 24 week period. The MUSCA study is the first clinical trial designed primarily to assess the effect of mepolizumab on disease-specific health-related quality of life using the St George's Respiratory Questionnaire (SGRQ) in patients with severe asthma with an eosinophilic phenotype. Using a series of questions that patients complete themselves, the SGRQ looks at how a patient's asthma symptoms impact on everyday activities, such as walking, housework, going to the shops, gardening or light exercise, and whether their severe asthma prevents them from doing activities they might otherwise expect to do.

For more information about the MUSCA study design please see MUSCA infographic

About severe asthma with an eosinophilic phenotype
Severe asthma is a chronic condition that affects a small, but significant, number of patients who need to take multiple medications to control their day-to-day symptoms and reduce the risk of frequent and serious asthma attacks. It is estimated that 5 - 10% of all asthma patients have severe asthma. In a sub-set of severe asthma patients, the over-production of eosinophils (a type of white blood cell) is known to cause inflammation in the lungs that can affect the airways, making breathing difficult and increasing the frequency of asthma attacks. People who have severe asthma with an eosinophilic phenotype are some of the most difficult asthma patients to treat.

For more information on the role of eosinophils in severe asthma please see GSK's infographic

About Nucala

Nucala is the first-in-class anti-IL-5 biologic therapy. Nucala was specifically developed to treat appropriate severe asthma patients whose condition is driven by inflammation caused by eosinophils. Nucala binds to the signalling protein IL-5, preventing it from binding to its receptor on the surface of eosinophils. Inhibiting IL-5 binding in this way reduces blood, tissue and sputum eosinophil levels. The mechanism of mepolizumab action in asthma has not been definitively established.

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 is not approved for the treatment of other eosinophilic conditions or 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

Nucala has also been approved in Canada, Australia, Japan, Switzerland, Chile, South Korea and Taiwan. Further regulatory applications have been submitted and are under review in other countries.

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

Important Safety 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.

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.

INFORMATION FOR US AUDIENCES ONLY - USE IN SPECIFIC POPULATIONS

A pregnancy exposure registry monitors pregnancy outcomes in women exposed to Nucala during pregnancy. Healthcare providers can enrol patients or encourage patients to enrol themselves by calling 1-877-311-8972 or visiting www.mothertobaby.org/asthma.

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 - 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.

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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 'Risk factors' in the company's Annual Report on Form 20-F for 2015.

Registered in England & Wales:
No. 3888792

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980 Great West Road
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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: March 06, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc