GLAXOSMITHKLINE PLC
Form 6-K
November 23, 2016

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 23 November 2016

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: Wednesday 23 November 2016, London UK - LSE Announcement

GSK announces phase lll study of mepolizumab meets co-primary endpoints and all secondary endpoints in patients with eosinophilic granulomatosis with polyangiitis

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that both co-primary endpoints and all secondary endpoints were met in a pivotal phase III study investigating the efficacy and safety of mepolizumab, an IL-5 antagonist, in patients with relapsing and refractory Eosinophilic Granulomatosis with Polyangiitis (EGPA), a rare disease characterised by widespread inflammation in the walls of small blood vessels (vasculitis).

A key goal of treatment for EGPA is to induce and maintain remission while reducing the use of corticosteroids and other immunosuppressive therapies. The co-primary endpoints for this 52-week study assessed the total duration of remission and the proportion of patients that achieved sustained remission following treatment with mepolizumab compared to treatment with placebo, both on top of standard of care. Remission for these two endpoints was defined by a Birmingham Vasculitis Activity Score (BVAS), a scoring system to assess disease activity, of 0 and corticosteroid dose <4mg/day prednisolone/prednisone. The difference between the two treatment groups was statistically significant for both co-primary endpoints as defined, respectively, by:

- The duration of remission as defined by the proportion of patients achieving at least 24 weeks duration of remission, one of five pre-defined categories of duration, was 19/68 (28%) for mepolizumab and 2/68 (3%) for placebo (P<0.001).

- The proportion of patients achieving remission at both weeks 36 and 48 of the study treatment period. This was 22/68 (32%) for mepolizumab and 2/68 (3%) for placebo (P<0.001).

The study included six secondary endpoints investigating relapse, remission and corticosteroid use, all considered clinically relevant for patients with EGPA. Patients demonstrated statistically significant differences, in favour of mepolizumab, for all secondary endpoints compared to placebo.

Steve Yancey, Vice President and Medicine Development Lead for mepolizumab, GSK said: "We are very pleased to observe the positive benefits of treatment with mepolizumab across several clinically relevant measures in this first ever double-blind, placebo-controlled study in patients with Eosinophilic Granulomatosis with Polyangiitis. Given that patients with this rare systemic inflammatory disease have limited treatment options, these results represent a significant step forward in our efforts to help them. We now look forward to progressing our regulatory submission plans."

Most frequent on-treatment serious adverse events reported for mepolizumab and placebo, respectively were asthma (4%, 4%), influenza (0, 3%) and pneumonia (0, 3%). One death was reported in a patient receiving mepolizumab which was not considered by the investigator to be related to study treatment.

Mepolizumab is not approved for use anywhere in the world for EGPA.

It is approved for use in the E.U., under the brand name Nucala®, for use as an add-on treatment for severe refractory eosinophilic asthma in adult patients.

Nucala is approved for use in the U.S. as an add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. It is not approved for the treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus.

Nucala has also been approved in Canada, Australia, Japan, Switzerland, Chile, South Korea and Taiwan.

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

Results of this study in patients with relapsing and refractory EGPA will support GSK's plans to submit regulatory applications for this patient population, expected in 2017. Full results from the study, including data from the secondary endpoints, will be submitted for presentation at an upcoming scientific congress and for publication in a peer-reviewed journal.

The study was conducted as part of an agreement between GSK and the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health, demonstrating an example of industry - public body collaboration in the field of rare disease drug development. Through this collaboration the mechanisms that underlie EGPA were also investigated, with potential future benefits for patients.

About Eosinophilic Granulomatosis with Polyangiitis (Churg-Strauss Syndrome)
EGPA, previously known as Churg-Strauss syndrome, is one of the rarest systemic vasculitic (inflammation of blood vessel walls) diseases. The global incidence is generally reported to be in the range 1.0 - 4.0 per million, with an estimated prevalence of approximately 14 - 45 per million. The mean age of diagnosis is 48 years. EGPA can affect multiple organs, including the heart, lungs, skin, gastrointestinal tract, kidneys, and nervous system, with varying symptoms, depending on which organs are affected, and to what extent. The disease can be life-threatening for some patients. While symptoms vary from one patient to another, almost all have asthma and/or nasal sinus polyps and blood eosinophilia.

The current approach to disease management is primarily based on reduction of active inflammation and suppression of the immune response through the use of corticosteroid therapy with concomitant immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil) and/or cytotoxic agents (e.g., cyclophosphamide). Although the use of these treatments can be effective for establishing remission, patients remain vulnerable to either the complications of the long-term use of these therapies, or to the risk of relapse, particularly if the dose of corticosteroid is reduced.

About study
The pivotal phase III study, MEA115921, was a randomised, double-blind study with the purpose to investigate the efficacy and safety of mepolizumab 300mg (administered subcutaneously every 4 weeks) compared with placebo over a 52-week study treatment period in 136 patients with relapsing or refractory EGPA receiving standard of care therapy including background corticosteroid therapy with or without immunosuppressive therapy.

About mepolizumab
Mepolizumab is a humanised IgG monoclonal antibody specific for interleukin 5 (IL-5). It is one of the ~40 assets profiled to investors at GSK's R&D event in November 2015 and belongs to the company's respiratory portfolio - one of six core areas of scientific research and development alongside immuno-inflammation, oncology, vaccines and infectious and rare diseases.

IL-5 is a cytokine which regulates the growth, activation and survival of eosinophils (white blood cells) and provides an essential signal for the movement of eosinophils from the bone marrow into the lung and other organs. Mepolizumab binds to human IL-5, stopping it from binding to its receptor on the surface of eosinophils. Inhibiting IL-5 binding in this manner reduces blood, tissue and sputum eosinophil levels, which in turn reduces eosinophil-mediated inflammation.

Important safety information
The following information is based on the Highlights section of the US Prescribing Information for Nucala (mepolizumab). 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., 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, 10% of subjects who received Nucala experienced systemic (allergic and nonallergic) and local site reactions compared to 7% 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: Injection site reactions (e.g. pain, erythema, swelling, itching, and 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

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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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 23, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc