GLAXOSMITHKLINE PLC
Form 6-K
December 12, 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 12 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: Tuesday 12 December 2017, London UK

GSK achieves approval for Nucala (mepolizumab) for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) for adults in the US

First targeted treatment approved for this rare eosinophil-driven disease, following FDA Priority Review

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved Nucala (mepolizumab) as the first targeted treatment for eosinophilic granulomatosis with polyangiitis (EGPA), previously known as Churg-Strauss syndrome. GSK submitted a supplemental Biologics License Application (sBLA) for mepolizumab, an interleukin-5 (IL-5) antagonist, in June 2017.

Eric Dube, Senior Vice President & Head, GSK Global Respiratory Franchise, said: "Following physician and patient experience with Nucala in severe eosinophilic asthma, we are thrilled that the FDA has expanded the use of this medicine to patients with EGPA, another eosinophil-driven disease, enabling GSK to make it available to patients. This approval follows the positive results of the largest prospective treatment study conducted in EGPA to date, and now for the first time physicians have a targeted treatment option for this debilitating condition." Mepolizumab is not approved for the treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus.

The approval for EGPA is based on results from the pivotal, 52-week, Phase III MIRRA1 study, conducted as a collaboration between GSK and the National Institute of Allergy and Infectious Diseases, part of the US National Institutes of Health.

The MIRRA study evaluated the efficacy and safety of 300mg of mepolizumab administered subcutaneously every four weeks versus placebo as add-on therapy to standard of care (corticosteroids plus or minus immunosuppressants) in 136 patients with relapsing and/or refractory EGPA:

- both co-primary endpoints (accrued time in remission and proportion of patients achieving remission at both weeks 36 and 48) were statistically significant in favour of mepolizumab

- all six secondary endpoints (investigating relapse, remission, and corticosteroid use) were met in favour of mepolizumab

- the percentage of patients experiencing on-treatment adverse events was comparable between the two treatment groups (97% mepolizumab versus 94% placebo). Injection site reactions (e.g., pain, erythema, swelling) occurred at a rate of 15% in patients receiving mepolizumab compared with 13% in patients receiving placebo. Eighteen percent of patients receiving mepolizumab reported serious adverse events compared with 26% in the placebo group, with the most frequently reported being asthma worsening/exacerbation (3% versus 6%).

Dr. Peter A. Merkel, Chief, Division of Rheumatology at Perelman School of Medicine, University of Pennsylvania & MIRRA study site investigator said: "Patients suffering from EGPA too often face a frustrating journey from a delay in receiving a proper diagnosis to having few effective treatment options with an acceptable safety profile. Rheumatologists, immunologists, and pulmonologists have an important role in properly diagnosing and treating patients with EGPA. Today's approval of mepolizumab provides specialists with the ability to offer a targeted treatment to appropriate patients with this complex disease."

Dr. Michael E. Wechsler, Professor of Medicine at National Jewish Health in Denver, Colorado, US & Principal Investigator of the MIRRA study, said: "Patients with EGPA often suffer from recurrent relapses that place them at greater risk of permanent tissue and organ damage. Clinical data demonstrated that mepolizumab increased accrued time in remission, reduced the frequency of relapse and flares, and enabled patients to have their dose of corticosteroid reduced compared to placebo in patients already receiving standard of care. These are key treatment goals and this approval is an important milestone both for treating physicians and for patients."

Nucala for treatment of EGPA in the US is available now. In recognition of the fact that US consumers are increasingly being asked by their insurers to take on more cost sharing, making affordability a concern for some patients, GSK has various patient assistance programmes available for those who qualify.

About EGPA
Eosinophilic granulomatosis with polyangiitis is a chronic rare disease that is caused by inflammation in the walls of small-to-medium sized blood vessels (vasculitis). The global incidence is generally reported to be in the range of 1-4 per million, with an estimated prevalence of approximately 14-45 per million. This translates to approximately 5000 patients with EGPA in the U.S. The mean age of diagnosis is 48 years, and the disease can be life-threatening for some patients.

In EGPA, patients typically develop adult-onset asthma, and often allergic rhinitis and sinusitis. EGPA can result in damage to lungs, sinuses, skin, heart, gastrointestinal tract, nerves and other organs. The most common symptoms include extreme fatigue, muscle and joint pain, weight loss, sinonasal symptoms, and breathlessness.

The current approach to disease management is primarily based on reduction of active inflammation and suppression of the immune response through the use of corticosteroids and 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 and to the risk of relapse, particularly if the dose of corticosteroid is reduced.

About Nucala (mepolizumab)
First approved in 2015 for severe eosinophilic asthma, mepolizumab is a targeted biologic therapy developed to treat diseases which 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.

Mepolizumab 100mg is approved for the 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).

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.

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.

Important Safety Information (ISI) for Nucala (mepolizumab)
This following ISI is based on the Highlights section of the US Prescribing Information for Nucala. Please consult the full Prescribing Information for all the labeled safety information for Nucala.

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

Hypersensitivity reactions (e.g. anaphylaxis, angioedema, bronchospasms, hypotension, urticaria, rash) have occurred after administration of Nucala. Discontinue Nucala in the event of a hypersensitivity reaction.

Do not use Nucala to treat acute bronchospasms or status asthmaticus.

Herpes zoster has occurred in subjects receiving Nucala in controlled clinical trials. Consider vaccination if medically appropriate.

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with Nucala. Reductions in corticosteroids dose, if appropriate, should be gradual and performed under the direct supervision of a physician.

Treat patients with pre-existing helminth infections before therapy with Nucala. If patients become infected while receiving treatment with Nucala and do not respond to anti-helminth treatment, discontinue Nucala until parasitic infection resolves.

The most common adverse reactions reported for Nucala (incidence ≥5%) include headache, injection site reaction, back pain and fatigue.

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.

Reference
1. Wechsler M et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. NEJM;2017:376

Notes to Editors:
Dr. Peter Merkel and Dr. Mike Wechsler have been contracted by GSK as consultants.

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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:
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: December 12, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc