GLAXOSMITHKLINE PLC
Form 6-K
September 10, 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 10 September 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: 7 September 2018, London UK - LSE Announcement

GSK receives complete response letter from US FDA for use of mepolizumab in COPD patients

GlaxoSmithKline plc (LSE/NYSE: GSK) today received a complete response letter (CRL) from the US FDA regarding its application for mepolizumab as an add-on treatment to inhaled corticosteroid-based maintenance treatment for the reduction of exacerbations in patients with chronic obstructive pulmonary disease (COPD), guided by blood eosinophil counts.

The CRL states that more clinical data are required to support an approval. GSK will work closely with the FDA to determine the appropriate next steps for the supplementary biologics licence application (sBLA).

About mepolizumab

First approved in 2015 for severe eosinophilic asthma, and also licenced for EGPA in the US, mepolizumab is the first-in-class monoclonal antibody that targets IL-5. It is believed to work by preventing IL-5 from binding to its receptor on the surface of eosinophils. Inhibiting IL-5 binding in this way reduces blood eosinophils.

Mepolizumab has been studied in over 3000 patients in 16 clinical trials across a number of eosinophilic indications and is currently being investigated for severe hypereosinophilic syndrome and nasal polyposis, in addition to the sBLA filed for the treatment of patients with COPD.

GSK in 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 five 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.

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 2017.

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
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: September 10, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc