GLAXOSMITHKLINE PLC
Form 6-K
December 16, 2015

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 December 2015

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

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Issued: Wednesday 16 December 2015, London UK - LSE Announcement

GSK receives positive top-line results from sirukumab phase III programme supporting regulatory filings for rheumatoid arthritis in 2016

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced it has received positive top-line results from the phase III programme investigating sirukumab, a human anti-interleukin (IL)-6 monoclonal antibody for the treatment of patients with moderately to severely active rheumatoid arthritis (RA), in development as part of a collaboration with Janssen Biologics (Ireland) [Janssen].

There were no unexpected safety findings relative to the known effects of anti-IL-6 inhibitors. Long term safety and efficacy data are currently being collected in ongoing extensions of the phase III trials. Regulatory applications for sirukumab for RA are anticipated in 2016.

Full results from the three pivotal studies will be presented at forthcoming scientific conferences and submitted for publication in peer-reviewed journals.

Sirukumab is currently not approved as a treatment for any indication anywhere in the world.

About the studies
SIRROUND-D (CNTO136ARA3002) is a multicentre, randomised, double-blind, placebo-controlled, parallel group study in 1670 patients with moderately to severely active RA who were unresponsive to disease-modifying antirheumatic drugs (DMARDs). The primary objective was to assess the efficacy of subcutaneous sirukumab as measured by the reduction of the signs and symptoms of RA and inhibition of radiographic progression.

SIRROUND-H (CNTO136ARA3005) is a multicentre, randomised, double-blind, parallel-group study comparing subcutaneous sirukumab with adalimumab (an anti-tumor necrosis factor (TNF) monoclonal antibody), each given as monotherapy in 559 biologic naïve patients with moderately to severely active RA who were intolerant to methotrexate, who were considered inappropriate for treatment with methotrexate or who were unresponsive to methotrexate. The primary objective was to assess the efficacy of each treatment as monotherapy.

SIRROUND-T (CNTO136ARA3003) is a multicentre, randomised, double-blind, placebo-controlled, parallel group study of sirukumab in 878 patients with active RA who were unresponsive or intolerant to anti-TNF agents. The primary objective was to assess the efficacy of subcutaneous sirukumab as measured by the reduction of the signs and symptoms of RA.

About sirukumab
Sirukumab is an investigational human anti-IL-6 monoclonal antibody that selectively binds with high affinity to the IL-6 cytokine, a naturally occurring protein that is believed to play a role in autoimmune conditions.

About the phase III programme
The global phase III clinical programme in patients with active RA comprises five studies investigating sirukumab 50mg and 100mg administered subcutaneously in combination with conventional DMARDs or as monotherapy every four or two weeks, respectively.

The studies comprise Japanese patients (SIRROUND-M) unresponsive to methotrexate or sulfasalazine, patients unresponsive to DMARDs (SIRROUND-D); sirukumab monotherapy in comparison with adalimumab in biologic naïve patients unresponsive to DMARDs (SIRROUND-H); patients unresponsive to anti-TNF agents and other biologic agents (SIRROUND-T); and a long-term extension study for patients completing SIRROUND-D and

SIRROUND-T (SIRROUND-LTE).

About the collaboration
In December 2011, Janssen and GSK entered into a co-development and co-commercialisation license agreement with respect to sirukumab for RA. Prior to the agreement, Janssen had been developing sirukumab for RA.

As part of the collaboration, a phase III programme began in August 2012 to investigate sirukumab for the treatment of moderately to severely active RA. The agreement gives both companies the option to investigate sirukumab for other indications beyond RA. GSK announced the start of a phase III study of sirukumab for patients with Giant Cell Arteritis (GCA) in November 2015.

About rheumatoid arthritis
Rheumatoid arthritis is a chronic, systemic inflammatory condition that is often characterised by symptoms that include pain, stiffness and inflammation, and in some cases, joint destruction and disability. It is estimated that 1.5 million Americans and more than 23.5 million people worldwide are affected by the condition, for which there is no cure.

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 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 'Risk factors' in the company's Annual Report on Form 20-F for 2014.

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: December 16, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc