GLAXOSMITHKLINE PLC
Form 6-K
June 08, 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 08 June 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

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Issued: Wednesday 8 June 2016, London UK, LSE Announcement

GSK announces phase III study of sirukumab meets both co-primary endpoints in patients with rheumatoid arthritis

- Plans on track to submit regulatory applications in Q3 2016

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that a pivotal global phase III study investigating subcutaneous sirukumab, a human anti-interleukin (IL)-6 monoclonal antibody, in adult patients with moderately to severely active rheumatoid arthritis (RA) met both co-primary end points.

The results from the positive SIRROUND-D study are being presented at the Annual European Congress of Rheumatology (EULAR 2016) in London, UK. Topline results were previously announced in December 2015.

Sirukumab is being co-developed as part of a collaboration with Janssen Biologics (Ireland) [Janssen].

The co-primary endpoints of the SIRROUND-D study in RA patients who had an inadequate response to treatment with disease-modifying anti-rheumatic drugs (DMARDs) showed that:

- Inhibition of radiographic progression, or joint destruction, was significantly greater among sirukumab-treated patients, with a mean change from baseline to week 52 in the van der Heijde-Sharp score of 0.50 among patients receiving sirukumab 50mg every four weeks (n=557) and 0.46 for patients receiving sirukumab 100mg every two weeks (n=557) compared with 3.69 among the placebo group (n=556) (both $P < 0.001$). The van der Heijde-Sharp scoring method is an X-ray measure of changes in joint destruction and damage, including joint erosion and joint space narrowing. With this method, higher scores indicate greater structural damage while lower scores indicate less structural damage. Significant inhibition of radiographic progression was demonstrated in both patients naïve to biologic therapy and those treated with biologics in the past, and was seen as early as week 24.

- At least a 20 percent improvement in RA signs and symptoms as measured by the American College of Rheumatology response criteria (ACR20) at week 16 was achieved by 54.8 percent and 53.5 percent of patients receiving sirukumab 50mg and sirukumab 100mg, respectively, compared with 26.4 percent of the placebo group (both $P < 0.001$).

All major secondary endpoints were also met with statistical significance for both doses of sirukumab versus placebo ($p<0.001$ for all measures across both doses). These were the change from baseline in the health assessment questionnaire disability index (HAQ-DI), percentage of patients achieving a 50 percent improvement in RA symptoms (ACR50), percentage of patients with improved disease activity score in 28 joints (DAS28) at week 24, and percentage of patients achieving at least a 70 percent improvement in RA signs and symptoms (ACR70) for 6 consecutive months (major clinical response) by week 52.

Paul-Peter Tak, GSK's Chief Immunology Officer & Senior Vice President R&D Pipeline, said: "Many patients with rheumatoid arthritis continue to suffer with this debilitating and painful disease despite the availability of several treatment options. This study showed that sirukumab inhibited the progression of joint damage and improved the signs

and symptoms of disease, disability and quality of life measures. These effects were seen with both the 100mg dose taken every two weeks and the 50mg dose taken every four weeks."

In the 18-week control period, the proportion of patients experiencing adverse events (AEs) and serious AEs, respectively, was higher with sirukumab 50mg (79.6 percent and 11.0 percent) and sirukumab 100mg (80.2 percent and 9.8 percent) versus placebo (65.5 percent and 6.8 percent), with the most common (at least 8 percent) AEs being elevated liver enzymes, upper respiratory tract infection, injection site erythema and nasopharyngitis. Through week 52, types of AEs and SAEs were similar to placebo. Prior to week 18, the formal placebo-controlled period, three patients died, one in each treatment group (placebo, sirukumab 50mg and sirukumab 100mg). From week 18 to week 52, there were eight deaths: three in the group originally on placebo that switched to sirukumab 50mg, three in the sirukumab 50mg and two in the sirukumab 100mg. Long-term safety and efficacy data are currently being collected in ongoing extensions of the three phase III trials.

Sirukumab is an investigational human monoclonal IgG1 kappa antibody that selectively binds with high affinity to the IL-6 cytokine, a naturally occurring protein that plays a role in autoimmune conditions. 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 immuno-inflammation portfolio - one of six core areas of scientific research and development alongside oncology, vaccines and infectious, respiratory and rare diseases. Global regulatory applications for sirukumab for RA are anticipated in Q3 2016. Sirukumab is currently not approved as a treatment for any indication anywhere in the world.

The results of the SIRROUND-D study will be presented at the Annual European Congress of Rheumatology (EULAR 2016) on Saturday 11 June 2016 (poster session: safety and efficacy of non-TNFa blockers in the treatment of RA - 2, SAT0145).

Additional abstracts reporting patient-reported outcomes (PRO) and other clinical efficacy and safety data in the SIRROUND-D study will be presented at the meeting and/or published in the abstract book. The PRO results show that sirukumab improved health-related outcomes including physical and emotional well-being and fatigue (SAT0167), morning stiffness (AB0341) and work productivity/interference (AB0378) associated with moderately to severely active RA. The clinical data include a post-hoc sub-group analysis showing improvements on radiographic progression in biologic-naive and biologic experienced patients (SAT0158) and a pooled analysis showing no clear dose-dependent effect of laboratory results from two sirukumab studies (SAT0166).

About the SIRROUND-D study
The SIRROUND-D (CNTO136ARA3002) study is a multicentre, randomised, double-blind, placebo-controlled, parallel group study in patients with moderately to severely active RA who had an inadequate response 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. A total of 1,670 patients were randomised evenly to receive sirukumab 50mg every 4 weeks or sirukumab 100mg every 2 weeks or placebo. This study is ongoing, but not recruiting participants and is estimated to complete by January 2017.

About the phase III programme
The sirukumab phase III clinical programme in patients with active RA involves more than 3,000 patients, the largest RA trial programme investigating an anti-IL-6 biologic therapy. In addition to the SIRROUND-D study, the other studies in the programme are:

- SIRROUND-T study: in patients with an inadequate response to anti-TNF agents and other biologic agents. This study has completed.
- SIRROUND-H study: in patients with an inadequate response or were intolerant to methotrexate (MTX) or for whom MTX was inappropriate. This study is estimated to complete in September 2016).

- SIRROUND-M study: in Japanese patients who had an inadequate response to MTX or sulfasalazine. This study has completed.
- SIRROUND-LTE study: a long-term extension study for patients completing SIRROUND-D and SIRROUND-T. This study is estimated to complete in 2020.

Results from these studies will be presented at forthcoming scientific conferences and all study results will be submitted for publication in peer-reviewed journals.

About the collaboration
In December 2011, Janssen and GSK entered into a licensing and co-development agreement with respect to sirukumab. 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. In November 2015 GSK announced the start of a phase III study of sirukumab for patients with Giant Cell Arteritis (GCA), and plans to start a study in asthma were disclosed at GSK's R&D day.

About rheumatoid arthritis
Rheumatoid arthritis is a chronic, systemic inflammatory condition that is characterised by pain, joint swelling, stiffness, joint destruction and disability. It is estimated 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 2015.

Registered in England & Wales:
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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: June 08, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc