GLAXOSMITHKLINE PLC
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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 16 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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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 16 November 2016, London UK - LSE announcement

GSK announces new data from phase III studies of sirukumab in adult patients with moderately to severely active rheumatoid arthritis

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced results from two pivotal phase III studies evaluating subcutaneous sirukumab, a human anti-interleukin (IL)-6 monoclonal antibody in development for the treatment of adults with moderately to severely active rheumatoid arthritis (RA).

The first study (SIRROUND-T), in patients who were refractory to or intolerant to one or more anti-tumor necrosis factor (TNF) agents, demonstrated that sirukumab met the primary endpoint showing significant improvement in the signs and symptoms of moderately to severely active RA compared to placebo. The second study (SIRROUND-H), a head-to-head study in patients who were refractory to or intolerant to methotrexate (MTX), demonstrated that sirukumab monotherapy met the first of two co-primary endpoints showing significant improvement in disease activity compared to adalimumab monotherapy.

The full results are being presented for the first time during oral sessions at the Annual Meeting of the American College of Rheumatology/Association for Rheumatology Health Professionals Meeting (ACR/ARHP 2016).

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

The SIRROUND-T study investigated sirukumab in adult patients with moderately to severely active RA who were refractory to or intolerant to one or more anti-TNF agents, which are often the first biological agents prescribed when a patient has failed treatment with a disease-modifying anti-rheumatic drug (DMARD). Approximately 40 percent of patients had prior exposure to both anti-TNF therapy and biologic therapy other than anti-TNFs, and 19 percent of patients were receiving sirukumab as monotherapy. Key results reported (Abstract 3223):

- A significantly higher proportion of sirukumab treated patients (40 percent with 50mg every four weeks and 45 percent with 100mg every two weeks) achieved at least a 20 percent improvement in signs and symptoms (ACR20) at week 16, the study's primary endpoint, compared with placebo (24 percent); $P \leq 0.001$.
- Statistically significant improvements for all major secondary endpoints for sirukumab treated patients compared with placebo. These were the change from baseline in the health assessment questionnaire disability index (HAQ-DI), percentage of patients achieving at least a 50 percent improvement in signs and symptoms (ACR50) and percentage of patients with improved disease activity score in 28 joints (DAS28 remission) at week 24; $P \leq 0.001$ for all measures. These improvements were seen as early as week 4 and maintained with sirukumab therapy through week 52.
- Statistically significant improvements were also observed for sirukumab treated patients compared to placebo for other patient reported outcomes including the physical and mental components of the SF-36, a patient reported survey of health status from baseline at week 24; $P < 0.01$.

The SIRROUND-H study compared sirukumab monotherapy with adalimumab monotherapy, an approved anti-TNF agent, in adult patients with moderately to severely active RA who were refractory to, or were intolerant to or inappropriate for MTX, a type of DMARD. Key results reported
(Abstract 3222):

- Significantly greater improvements in disease activity, as assessed by DAS28, in sirukumab treated patients (mean change from baseline of -2.58 with 50mg, -2.96 with 100mg) at week 24, the first of two co-primary endpoints of the study, compared to adalimumab treated patients (-2.19 with 40mg every 2 weeks); $P = 0.013$ and $P < 0.001$, respectively.
- Clinically relevant improvements in signs and symptoms of disease, as assessed by ACR50, the second of two co-primary endpoints, at week 24 for all treatment groups, although differences were not statistically significant between sirukumab 50mg, sirukumab 100mg and adalimumab 40mg (27 percent, 35 percent and 32 percent,

respectively; P > 0.05).
- A clinically relevant proportion of patients in all three treatment groups attained both major secondary endpoints of DAS28 remission (13 percent with sirukumab 50mg, 20 percent with sirukumab 100mg, 8 percent with adalimumab 40mg) and ACR20 response at week 24
(54 percent with sirukumab 50mg, 59 percent with sirukumab 100mg, 57 percent with adalimumab; P > 0.05).

Paul-Peter Tak, GSK's Chief Immunology Officer & Senior Vice President, R&D Pipeline, said: "Patients suffering with rheumatoid arthritis need access to a range of treatment options during different stages of their long-term disease. The results presented today show that both doses of sirukumab tested, including a 50mg subcutaneous dose taken every four weeks, reduced the signs and symptoms and disease activity in difficult-to-treat patients who had failed both conventional and biologic therapy."

In the SIRROUND-T study, through week 24 of the study (the placebo controlled phase), the incidence of patients reporting adverse events (AEs) was 66 percent, 71 percent and 62 percent for sirukumab 50mg, sirukumab 100mg and placebo, respectively. The incidence of patients reporting serious AEs was 10 percent, 8 percent and 5 percent for sirukumab 50mg, sirukumab 100mg and placebo, respectively. Most common AEs (incidence >5% in any treatment group) were injection-site erythema, ALT increased, nasopharyngitis, injection-sire pruritus, upper respiratory infection, rheumatoid arthritis, and injection-site reaction. No deaths were reported through week 24. Through week 52 (not placebo-controlled), the incidences of AEs was 80 percent and 81 percent for sirukumab 50mg and sirukumab 100mg, respectively. The incidence of patients reporting serious AEs were 14 percent and 13 percent, for sirukumab 50mg and sirukumab 100mg, respectively. There were five deaths reported through week 52 (two in the sirukumab 50mg group and three in the sirukumab 100mg group).

In the SIRROUND-H study, through week 24 of the study, the incidence of patients reporting AEs was 57 percent, 64 percent and 55 percent for sirukumab 50mg, sirukumab 100mg and adalimumab, respectively. The incidence of patients reporting serious AEs was 7 percent, 3 percent and 4 percent with sirukumab 50mg, sirukumab 100mg and adalimumab, respectively. There were no deaths reported through week 24. The rate of reported infections was 20 percent, 24 percent and 19 percent for sirukumab 50mg, sirukumab 100mg and adalimumab, respectively. The rate of serious infections was 3 percent, 0 percent and 1 percent for sirukumab 50mg, sirukumab 100mg and adalimumab, respectively. The reported incidence of injection-site reactions was dose-related for sirukumab with
21 percent and 11 percent for sirukumab 100mg and sirukumab 50mg, respectively and 8 percent for adalimumab. No injection-site reactions were considered serious. Most common AEs for sirukumab (incidence >5% in any treatment group) were injection site erythema, ALT increased, AST increased, injection site pruritus, and neutropenia; the only AE that occurred at an incidence >5% for adalimumab was injection site erythema.

Additional abstracts reporting patient-reported outcomes (PRO) and other clinical efficacy and safety data from the SIRROUND-D and SIRROUND-T studies will be presented at the meeting and/or published in the ACR program book.

About SIRROUND-T and SIRROUND-H study designs
SIRROUND-T is a phase III randomised, double-blind, placebo-controlled study in 878 adult patients with moderately to severely active RA who were intolerant or refractory to anti-TNF therapy. The primary objective was to assess the safety and efficacy of sirukumab as measured by the reduction of the signs and symptoms of RA. Patients were randomised to receive sirukumab 50mg every 4 weeks or sirukumab 100mg every 2 weeks or placebo every 2 weeks. Patients with less than 20 percent improvement from baseline in both swollen and tender joint counts at weeks 18, or those still on placebo at week 24, were re-randomised to receive sirukumab 50mg every 4 weeks or 100mg every 2 weeks through week 52.

SIRROUND-H is a phase III randomised, double-blind, parallel-group study in 559 biologic-naive adult patients with moderately to severely active RA who were intolerant to MTX, considered inappropriate for MTX treatment for safety

reasons or were inadequate responders to MTX. The primary objective was to evaluate the safety and efficacy of sirukumab monotherapy compared with adalimumab monotherapy as measured by the reduction in disease activity and signs and symptoms of RA. Patients were randomised to receive sirukumab 50mg every 4 weeks or sirukumab 100mg every 2 weeks or adalimumab 40mg every 2 weeks as monotherapy.

About the phase III programme in rheumatoid arthritis
The phase III clinical programme in patients with active RA includes five studies investigating sirukumab 50mg and 100mg administered subcutaneously in combination with conventional DMARDs or as a monotherapy every four or two weeks, respectively. The comprehensive development program involves more than 3,000 patients.

- SIRROUND-D study: in patients who had an inadequate response to disease-modifying antirheumatic drugs (DMARDs).
- SIRROUND-T study: in patients who had an inadequate response or were intolerant to anti-TNFa agents
- SIRROUND-H study: in patients with an inadequate response or who were intolerant to methotrexate (MTX) or for whom MTX was inappropriate.
- SIRROUND-M study: in Japanese patients who had an inadequate response to MTX or sulfasalazine.
- SIRROUND-LTE study: a long-term extension study for patients completing SIRROUND-D and SIRROUND-T.

Top-line results of SIRROUND-D, SIRROUND-T and SIRROUND-H were announced in December 2015 and primary results from the SIRROUND-D study were announced in June 2016.

About Sirukumab
Sirukumab is a human monoclonal IgG1 kappa antibody that targets the cytokine IL-6, a naturally occurring protein that is believed to play a role in autoimmune conditions like RA. It is not approved as a treatment for RA or any other indication anywhere in the world.

In December 2011, Janssen and GSK entered into a licensing and co-development agreement with respect to sirukumab. Under the terms, Janssen retains commercialization rights in territories outside of the Americas including Europe and Asia Pacific, while GSK has exclusive rights to commercialize sirukumab in North, Central and South America. The agreement gives both companies the option to investigate sirukumab for other indications beyond RA. Sirukumab is currently being evaluated by health authorities in the U.S., EU and Japan as a subcutaneous therapy for the treatment of certain adult patients with moderately to severely active RA.

About Rheumatoid Arthritis
Rheumatoid arthritis is a chronic, systemic inflammatory condition that is characterized by pain, joint swelling, stiffness, joint destruction and disability. It is estimated that more than 23.5 million people worldwide are affected by the condition, for which there is no cure.[i]

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.

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[i] Centers for Disease Control and Prevention. "Rheumatoid Arthritis (RA)," Available at: http://www.cdc.gov/arthritis/basics/rheumatoid.htm. Accessed August 16, 2016.

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 16, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc