GLAXOSMITHKLINE PLC
Form 6-K
September 23, 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 23 September 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

Issued: 23 September 2016, London UK - LSE Announcement

GSK announces US regulatory submission for sirukumab in rheumatoid arthritis

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced the submission of a Biologics License Application (BLA) to the United States Food and Drug Administration (FDA) by Janssen Biotech, Inc., (JBI), seeking approval of a subcutaneous formulation of sirukumab, a human anti-interleukin (IL)-6 monoclonal antibody, for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have failed or are intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).

Sirukumab is being co-developed for RA as part of a collaboration with Janssen Biologics (Ireland) ("Janssen"), an affiliate of JBI.

Paul-Peter Tak, GSK's Chief Immunology Officer & Senior Vice President R&D Pipeline, said: "We are pleased with the progress being made to seek regulatory approval of sirukumab in adult patients who, despite the use of conventional and biologic therapies, still suffer from moderately to severely active rheumatoid arthritis. If approved, sirukumab would provide these patients with another treatment option. This US submission follows one made for Europe earlier this month and we look forward to the outcome of the regulatory authority reviews."

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.

Approval is being sought for the subcutaneous formulation of sirukumab in two presentations, a single-dose prefilled syringe and a single-dose autoinjector. The data to support the file are based on a comprehensive phase III clinical development programme involving more than 3,000 patients.

A regulatory submission to the European Medicines Agency (EMA) was announced on 12 September 2016. Sirukumab is currently not approved as a treatment for any indication anywhere in the world.

About the phase III clinical 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. Data has been generated from the completed and ongoing studies to support the file.

- 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 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. Primary results from the SIRROUND-T and SIRROUND-H studies will be presented at an upcoming scientific congress. Complete results for all studies will be submitted for publication in peer-reviewed journals.

About the collaboration

In December 2011, GSK and Janssen entered into a licensing and co-development agreement with respect to sirukumab. Under the terms, GSK has exclusive rights to commercialise sirukumab in North, Central and South America, while Janssen retains commercialisation rights in the rest of the world, including Europe. Global profit will be shared equally between the two companies. 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.
Janssen is responsible for the FDA and EMA regulatory files. The collaboration gives both companies the option to investigate sirukumab for other indications beyond RA. An ongoing GSK phase III study, announced in November 2015, is currently investigating sirukumab in Giant Cell Arteritis. In addition, plans to start a phase II study for asthma in 2016 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, disability and decreased quality of life. 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:
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 23, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc

229,448 1,435,660

4. To ratify the appointment of ParenteBeard LLC as the Company's independent registered public accounting firm for the year ending September 30, 2013.

FOR	AGAINST	ABSTAIN
5,983,070	2,012	97,386

Each of the Company's nominees were elected as directors, the proposal to adopt a non-binding resolution to approve the compensation of our named executive officers was adopted, every year received a plurality of votes cast on the advisory vote on the frequency of the non-binding resolution to approve the compensation of our named executive officers, and the proposal to ratify the appointment of ParenteBeard LLC as the Company's independent registered public accounting firm for the year ending September 30, 2013 was adopted by the shareholders of the Company at the Annual Meeting.

(c) Not applicable.

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 authorized.

MALVERN BANCORP, INC.

Date: February 7, 2013

By: /s/Ronald Anderson
Ronald Anderson
President and Chief Executive Officer