GLAXOSMITHKLINE PLC
Form 6-K
March 20, 2014

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 March 2014

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: 20 March 2014, London UK - LSE Announcement

Investigational MAGE-A3 antigen-specific cancer immunotherapeutic does not meet first co-primary endpoints in MAGRIT, a Phase III Non-small cell lung cancer clinical trial

- GSK will continue the trial in order to assess the third co-primary endpoint, which is disease-free survival in a gene signature positive sub-population

GlaxoSmithKline plc (LSE:GSK) today announced that analysis of the MAGRITi trial, a Phase III trial of its MAGE-A3 cancer immunotherapeuticii in non-small cell lung cancer (NSCLC) patients, showed that the trial did not meet its first or second co-primary endpoint as it did not significantly extend disease-free survival (DFSiii) when compared to placebo in either the overall MAGE-A3 positive population (first co-primary endpoint) or in those MAGE-A3-positive patients who did not receive chemotherapy (second co-primary endpoint). GSK currently remains blinded to the overall trial data from the analysis of the first two co-primary endpoints to allow for the unbiased generation of a mathematical model to assess the third co-primary endpointiv.

MAGRIT, a randomised, double-blind, placebo-controlled trial, is evaluating the efficacy and safety of the MAGE-A3 cancer immunotherapeutic in Stage IB, II and IIIA completely resected NSCLC patients whose tumours expressed the MAGE-A3 gene. Patients were given up to 13 intramuscular injections of either the MAGE-A3 immunotherapeutic or placebo over a period of 27 months.

MAGE-A3 is a tumour-specific antigen expressed in a variety of cancers but not in normal cells. In NSCLC, it is expressed in approximately one third of tumours in patients diagnosed with Stage IB-IIIA disease. The MAGRIT trial enrolled 2,312 MAGE-A3-positive patients across more than 400 sites in 34 countries worldwide.

The Independent Data Monitoring Committee (IDMC) indicated that its review of the current safety information raised no specific concern for the continuation of the trial and is in line with the known safety information for the MAGE-A3 cancer immunotherapeutic. As planned GSK will continue the trial in order to assess the third co-primary endpoint. This endpoint is designed to identify a subset of MAGE-A3 positive patients that may benefit from the treatment with the MAGE-A3 cancer immunotherapeutic. Results from a final analysis are expected in 2015.

Vincent Brichard, Senior Vice-President & Head of Immunotherapeutics, GSK Vaccines said: "We want to thank all patients, their families and healthcare workers for their involvement in the MAGRIT trial. We are disappointed that the trial did not demonstrate a benefit for overall MAGE-A3 positive patient population, but we remain committed to the effort to identify a sub-population of NSCLC patients who may benefit from this investigational treatment."

Phase III clinical study (DERMA)

GSK is continuing to evaluate in another Phase III clinical study (DERMA) whether a gene signature can identify a sub population of melanoma patients that would benefit from the same investigational MAGE-A3 cancer immunotherapeutic. This follows the read-out of the first co-primary endpoint in September 2013, of DFS in the overall MAGE-A3 positive population, which was not met. Work is progressing on the mathematical model to allow assessment of DFS in the gene signature population, the second co-primary endpoint in the study. The outcome is expected in 2015.

Notes to editors

i A double-blind, randomised, placebo-controlled Phase III trial to assess the efficacy of recMAGE-A3 + AS15 antigen-specific cancer immunotherapeutic as adjuvant therapy in patients with MAGE-A3 positive NSCLC.(MAGRIT, NCT00480025)

ii MAGE-A3 cancer immunotherapeutic consists of recombinant MAGE-A3 protein and a novel immunostimulant AS15 (a combination of QS-21 Stimulon® adjuvant, monophosphoryl lipid A, and CpG7909, a TLR-9 agonist, in a liposomal formulation). QS-21 Stimulon® adjuvant is licensed from Antigenics Inc, a wholly owned subsidiary of Agenus Inc. (NASDAQ: AGEN).

iii DFS is defined as the time from randomization to the date of first recurrence of the disease or death, whichever comes first.

iv Access to a small proportion of the data (the training set) will allow for the unbiased generation of a mathematical model to assess the third co-primary endpoint in the remainder of the data (the test set).

V A Whyte
Company Secretary

20 March 2014

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 2013.

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: March 20, 2014

By: VICTORIA WHYTE

Victoria Whyte

Authorised Signatory for and on
behalf of GlaxoSmithKline plc