GLAXOSMITHKLINE PLC
Form 6-K
September 05, 2013

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 September 2013

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: Thursday 5 September 2013, London UK

The investigational MAGE-A3 antigen-specific cancer immunotherapeutic does not meet first co-primary endpoint in Phase III melanoma clinical trial

In line with the Independent Data Monitoring Committee's (IDMC) unanimous recommendation, GSK will continue the DERMA trial until the second co-primary endpoint is assessed

GlaxoSmithKline plc (LSE:GSK) today announced that an independent analysis of the DERMAi study, a Phase III randomised, blinded, placebo-controlled trial of the MAGE-A3 cancer immunotherapeuticii showed that the study did not meet its first co-primary endpoint as it did not significantly extend disease-free survival (DFSiii) when compared to placebo in the MAGE-A3 positive population.

The DERMA study evaluated the efficacy and safety of the MAGE-A3 cancer immunotherapeutic in Stage IIIB/C melanoma patients with macroscopic nodal disease, whose tumours expressed the MAGE-A3 gene and had their tumours removed surgically. MAGE-A3 is a tumour-specific antigen that is expressed in a variety of cancers, including melanoma with no presentation in normal cells. MAGE-A3 is expressed in about 65% of Stage III melanomas.

In line with the Independent Data Monitoring Committee's (IDMC) unanimous recommendation, GSK will continue the DERMA trial until the second co-primary endpoint is assessed. This endpoint, DFS in the gene signature positive sub-population, is designed to identify a subset of MAGE-A3 positive patients that may benefit from the treatment. Results from this analysis are expected in 2015. Until then, GSK will remain blinded to all safety and efficacy data.

The IDMC for the DERMA study indicated that the current review of the safety information raised no concern for the continuation of the trial.

"We want to thank all patients, their families and healthcare workers for their involvement in the trial and we remain committed to identifying a patient sub-population who may benefit from this investigational treatment," commented Vincent Brichard, Senior Vice-President & Head of Immunotherapeutics, GSK Vaccines.

GSK is continuing to evaluate the same investigational MAGE-A3 cancer immunotherapeutic in another independent Phase III study (MAGRIT) in Non Small Cell Lung Cancer (NSCLC) following surgical removal of the primary tumour with first data anticipated in the first half of 2014.

S M Bicknell
Company Secretary

5 September 2013

Notes to editors

i A double-blind, randomized, placebo-controlled Phase III study to assess the efficacy of recMAGE-A3 + AS15 antigen-specific cancer immunotherapeutic as adjuvant therapy in patients with MAGE-A3 positive resected stage III melanoma.(DERMA)
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.

References

1. W.H.J. Kruit, S. Suciu, B. Dreno, L. Mortier, C. Robert, V. Chiarion-Sileni, M. Maio, A. Testori, T. Dorval, J-J. Grob, J.C. Becker, A. Spatz, A.M. Eggermont, J. Louahed, F.F. Lehmann, V.G. Brichard, and U. Keilholz. Selection of immunostimulant AS15 for active immunization with MAGE A3 protein: Results of a randomized Phase II study of the EORTC Melanoma Group in metastatic melanoma). J Clin Oncol. 2013;July 1(Vol 31, n 19):2413-2420
2. J. Vansteenkiste, M. Zielinski, A. Linder, J. Dahabreh, E.E. Gonzalez, W. Malinowski, M. Lopez-Brea, T. Vanakesa, J. Jassem, H. Kalofonos, J. Perdeus, R. Bonnet, J. Basko, R. Janilionis, B. Passlick, T. Treasure, M. Gillet, F.F. Lehmann, and V.G. Brichard. Adjuvant MAGE-A3 Immunotherapy in Resected Non-Small-Cell Lung Cancer: Phase II Randomized Study Results. J Clin Oncol. 2013;Jul 1(vol. 31 no. 19):2396-2403

GlaxoSmithKline
- 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

GlaxoSmithKline
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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. Factors that may affect GSK' s operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

Registered in England & Wales:
No. 3888792

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980 Great West Road
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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 05, 2013

By: SIMON BICKNELL

Simon Bicknell
Authorised Signatory for and on
behalf of GlaxoSmithKline plc