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Issued: 2 April 2014, London UK - LSE Announcement

Update on phase III clinical trial of investigational MAGE-A3 antigen-specific cancer immunotherapeutic in non-small cell lung cancer

GlaxoSmithKline plc (LSE:GSK) today announced its decision to stop the MAGRITi trial, a Phase III trial of its MAGE-A3ii cancer immunotherapeuticiii in non-small cell lung cancer (NSCLC) patients, after establishing that it will not be possible to identify a sub-population of gene-signature positive NSCLC patients that may benefit from the treatment.

Data from the trial announced on 20 March 2014 showed that it did not meet its first or second co-primary endpoints as it did not significantly extend disease-free survival (DFSiv) 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 continued with the MAGRIT trial to investigate the third co-primary endpoint of DFS in a gene signature positive sub-population, which was designed to identify a subset of MAGE-A3 positive patients that may benefit from the treatment. However, the pre-planned independent third-party analysis of a proportion of the datav (to identify a gene signature classifier) has concluded that assessment of the third co-primary endpoint is not feasible due to an insufficient treatment effect.

The trial will be stopped and GSK will now gain access to the un-blinded data, in order to conduct a full assessment of the findings and understand learnings for other aspects of immunotherapy development within GSK.

The Independent Data Monitoring Committee (IDMC) indicated that its review of the current safety information revealed no specific safety concern and the data is in line with the known safety information for the MAGE-A3 cancer immunotherapeutic.

MAGRIT, a randomised, double-blind, placebo-controlled trial, evaluated the efficacy and safety of the MAGE-A3 cancer immunotherapeutic in Stage IB, II and IIIA completely resected non-small cell lung cancer (NSCLC) patients whose tumours expressed the MAGE-A3 gene.

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 this research. While we are extremely disappointed to learn that this trial did not have a positive outcome for the patients who participated in this trial, we are very grateful to its participants. We hope that the data generated in this trial will advance our understanding of the science of immunotherapeutics, and ultimately towards development of new therapies."

Phase III clinical study (DERMA)

GSK is continuing to evaluate in another phase III clinical trial (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 (the gene signature classifier) to allow assessment of DFS in the gene signature population, the second co-primary endpoint in the DERMA trial. 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. Patients were given up to 13 intramuscular injections of either the MAGE-A3 immunotherapeutic or placebo over a period of 27 months. (MAGRIT, NCT00480025)

ii 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.

iii 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).

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

v Access to a small proportion of the data (the training set) by independent third party allowed for unbiased investigation into whether it was possible to generate a mathematical model to assess the third co-primary endpoint in the remainder of the data set.

V A Whyte
Company Secretary
2 April 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:
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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: April 02, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc