GLAXOSMITHKLINE PLC
Form 6-K
December 12, 2017

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 12 December 2017

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: Monday 11 December 2017, London UK

GSK presents promising new data for priority BCMA asset from its emerging Oncology pipeline at 59th ASH meeting

- 60% response rate in heavily pre-treated relapsed/refractory multiple myeloma patients in phase I/II DREAMM-1 study
- Investigational BCMA antibody-drug conjugate GSK2857916 recently awarded PRIME and Breakthrough Designations

GlaxoSmithKline plc (LSE/NYSE: GSK) today presented promising new data from the dose expansion phase of the DREAMM-1 study of GSK2857916, an investigational anti-B-cell maturation antigen (BCMA) antibody-drug conjugate. In this study of heavily pre-treated multiple myeloma patients (n=35), GSK2857916 monotherapy demonstrated a 60% response rate (95% confidence interval [CI]: 42.1% - 76.1%) and a median progression free survival of 7.9 months (95% CI: 3.1 - not estimable). Results were presented during an oral presentation at the 59th annual meeting of the American Society for Hematology (ASH).

Patients were enrolled in DREAMM-1 independent of BCMA expression levels. The study participants were heavily pre-treated, with 57% of the patients having at least five prior lines of treatment and 40% having prior daratumumab treatment. The most commonly reported adverse events were corneal events (63%) and thrombocytopenia (57%); no dose-limiting toxicities were reported. Infusion-related reactions (IRRs) occurred in 23% of patients (without pre-medication) on the first infusion and no IRRs occurred on subsequent infusions.

Axel Hoos, SVP Oncology R&D, GSK said "The patients participating in the DREAMM-1 trial had very limited options for further treatment, so we are encouraged by the response rate seen in this trial. GSK2857916 is the leading asset in our emerging pipeline of potentially transformative Oncology medicines and we plan to rapidly progress its development programme, initiating pivotal monotherapy studies as well as new combination studies in 2018."

Multiple myeloma is the second most common blood cancer in the United Statesi and is generally considered treatable but not curable. Multiple myeloma commonly becomes refractory to available treatments, so research into new treatments is vital. GSK2857916 was recently awarded Breakthrough Therapy designation from the US Food and Drug Administration and PRIME designation from the European Medicines Agency; these designations are intended to facilitate development of investigational medicines that have shown clinical promise for conditions where there is significant unmet need.

The DREAMM -1 study is a first-in-human, open-label study of GSK2857916 in patients with relapsed/ refractory multiple myeloma. The primary objective is safety; response rate, pharmacokinetics and immunogenicity are secondary endpoints. The study consists of two parts: a dose escalation phase in which patients received GSK2857916 at escalating doses and a dose expansion phase in which all patients received GSK2857916 at the recommended phase II dose. Results from the dose escalation phase of the study were presented at ASH 2016ii

GSK in Oncology
GSK is focused on delivering transformational therapies for cancer patients. GSK's pipeline is focused on immuno-oncology, cell therapy, and epigenetics. Our goal is to achieve a sustainable flow of new treatments for cancer patients based on a diversified portfolio of investigational medicines utilising modalities such as small molecules, antibodies, multi-specific molecules, adjuvants and cells, either alone or in combination.

The data presented at ASH show important R&D progress in GSK's Oncology pipeline. The company has also strengthened its commercial and R&D interface within Oncology through the recent appointment of Christine Roth as Oncology Franchise Head, who will be responsible for shaping the commercial and global product strategy for GSK's innovative pipeline of Oncology assets.

In 2015 GSK divested its Oncology business for an aggregate cash consideration of $16 billion, while retaining its portfolio of early stage Oncology assets. Novartis has a right of first negotiation (ROFN) that is triggered upon a decision to seek a partner or divest certain Oncology assets or if GSK proposes to seek a marketing authorisation for such Oncology assets, on an asset by asset basis. The ROFN does not oblige GSK to sell to, or partner with, Novartis. Novartis does not have an "opt-in" or a "call" option related to GSK's Oncology pipeline. Under the ROFN, GSK is able to continue to develop and commercialise assets on its own. GSK's obligation is to negotiate in good faith. GSK would only enter into a transaction if GSK believes it was in the best interest of its shareholders. The ROFN extends for 12.5 years from closing; i.e. September 2027.The complete contractual terms of the ROFN are available at https://www.sec.gov/Archives/edgar/data/1131399/000119312516510261/d32974dex410.htm

Conference call for investors and analysts
GSK will host a conference call for investors and analysts at 18:00 GMT/ 1:00PM EST on Tuesday, 12 December 2017.

Notes to Editors

About the DREAMM -1 study (NCT02064387)
The study is an open-label, dose escalation study to investigate the safety, pharmacokinetics, pharmacodynamics, immunogenicity and clinical activity of the antibody drug conjugate GSK2857916 in subjects with relapsed/refractory multiple myeloma and other advanced haematologic malignancies expressing BCMA.

The study consists of two parts:1) a dose escalation phase and 2) an expansion phase for safety, tolerability, PK, PD, and clinical activity testing. The study will enrol a total of approximately 80-95 subjects with relapsed/refractory MM or BCMA-expressing hematologic malignancies. The maximum dose to be administered in this trial will not exceed 5 mg/kg.

About B-cell maturation antigen (BCMA): The normal function of BCMA is to promote plasma cell survival by transduction of signals from two known ligands, BAFF and APRIL. This pathway has been shown to be important for myeloma cell growth and survival. BCMA expression is limited to B cells at later stages of development. BCMA is expressed at varying levels in myeloma patients and BCMA membrane expression is universally detected in myeloma cell linesiii.

About GSK2857916:
GSK2857916 is an antibody-drug conjugate comprising a humanised anti- B cell maturation antigen (BCMA) monoclonal antibody conjugated to the cytotoxic agent auristatin F via non-cleavable linker. The drug linker technology is licensed from Seattle Genetics; monoclonal antibody is produced using technology licensed from BioWa.

GSK2857916 is currently in phase I clinical development (NCT02064387) in patients with relapsed/refractory multiple myeloma and other advanced haematologic malignancies expressing BCMA.

GSK2857916 is not approved for use anywhere in the world

GSK - GSK - a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com

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Cautionary statement regarding forward-looking statementsGSK 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 'Principal risks and uncertainties' in the company's Annual Report on Form 20-F for 2016.

Registered in England & Wales:
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i https://www.cancer.net/cancer-types/multiple-myeloma/statistics Last accessed December 2017

iiAdam D. Cohen, Rakesh Popat, Suzanne Trudel, Paul G Richardson, Ed N. Libby III, Nikoletta Lendvai, Larry D. Anderson Jr., HeatherSutherland, Stephen DeWall, Catherine Ellis, Zangdong He, Jolly Mazumdar, Catherine Wang, Joanna B. Opalinska and Peter M. Voorhees. First in Human Study with GSK2857916, an Antibody Drug Conjugated to Microtubule-Disrupting Agent Directed Against B-Cell Maturation Antigen (BCMA) in Patients with Relapsed/Refractory Multiple Myeloma (MM): Results from Study BMA117159 Part 1 Dose Escalation. Blood 2016; 128(22):1148

iii Robert O. Carpenter, Moses O. Evbuomwan, [...], and James N. Kochenderfer. B-cell Maturation Antigen is a Promising Target for Adoptive T-cell Therapy of Multiple Myeloma. Clin Can Res

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: December 12, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc