GLAXOSMITHKLINE PLC
Form 6-K
March 21, 2019

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 21 March 2019

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: 21 March 2019, London UK - LSE Announcement

GSK announces further positive data from DREAMM-1 study of anti-BCMA antibody-drug conjugate in patients with relapsed/refractory multiple myeloma

Median progression-free survival extends to twelve months

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced further positive data from the DREAMM-1 study of patients with relapsed/refractory multiple myeloma who received GSK2857916, an investigational anti-B-cell maturation antigen (BCMA) antibody-drug conjugate. These results, published in Blood Cancer Journal (link) build upon results from the pre-specified interim analysis, which were first presented at the American Society of Haematology Congress in 2017.

These new data confirm that 60% of patients receiving GSK2857916 achieved an overall response rate (ORR). This ORR was identical to the rate previously reported in the interim analysis, after more than a year of follow-up, and demonstrates not only the potential efficacy of the medicine but the durability and depth of response. The number of patients achieving a complete response increased to 15% over this additional one year follow-up period. The median progression-free survival (PFS) was 12 months (95% CI [3.1-Not Estimable/NE]), an increase from the previously reported 7.9 months PFS. The median duration of response in the final analysis was 14.3 months (95% CI [10.6-NE]). All patients whose data were reported in the interim analysis were included in this analysis.

Dr Hal Barron, Chief Scientific Officer and President, R&D, GSK, commented, "These data are very encouraging and I am excited by what they could mean for people living with multiple myeloma. We are aggressively advancing this potential new medicine and plan to have pivotal data to support its filing by the end of this year."

A total of 35 patients were enrolled in Part 2 of the DREAMM-1 study independent of their BCMA expression levels. Amongst those heavily pre-treated patients not previously treated with the anti-CD38 monoclonal antibody, daratumumab, the ORR was 71% (95% CI [47.8%,88.7%]) with a mPFS of 15.7 months, (95% CI [2.3-NE]). In those patients who had previously been treated with daratumumab, the ORR was 38.5%; (95% CI [13.9-68.4]) with a mPFS of 7.9 months (95% CI [2.3-NE]).

No new safety signals were identified during this treatment period. The most commonly reported adverse events were thrombocytopenia (63%), blurred vision (51%), cough (40%), which were mostly mild or moderate (Grade 1 or 2). The most commonly reported Grade 3 or 4 adverse events were thrombocytopenia (35%) and anemia (17%) and were found to be manageable.

Paul Giusti, President and Chief Executive Officer of the Multiple Myeloma Research Foundation (MMRF), said, "Significant advancements have been made in our knowledge, understanding and the treatment of multiple myeloma in the past decade, but there is so much more that we as a community need to do to accelerate better outcomes and quality of life for patients. Relapses are particularly challenging, so the need for treatment advances is a priority at the MMRF to ensure our patients can benefit from them in the future. We are encouraged by the results from this early study, and we look forward to seeing additional data later this year."

Multiple myeloma is the second most common blood cancer in the United States[i] and is generally considered treatable but not curable. Multiple myeloma commonly becomes refractory to available treatments, so research into new treatments is vital.

In 2017, GSK2857916 was awarded Breakthrough Therapy designation from the U.S. 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.

About the DREAMM-1 study (NCT02064387)
DREAMM-1 is a first-in-human, open-label study of GSK2857916 to investigate the safety, pharmacokinetics, pharmacodynamics, immunogenicity and clinical activity of the antibody drug conjugate GSK2857916 in patients with relapsed/refractory multiple myeloma and other advanced haematologic malignancies expressing BCMA. The primary objective is safety; additional objectives include: response rate, pharmacokinetics and immunogenicity. 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 2 dose.

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 lines[iii].

About the DREAMM Clinical Trial Programme for GSK2857916 (GSK'916)
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.

GSK'916 is currently in clinical development in patients with relapsed/refractory multiple myeloma and other advanced haematologic malignancies expressing BCMA.

Trial Name	GSK ID/NCT ID	Status	Design
DREAMM-1	117159/ NCT02064387	Completed	
DREAMM-2	205678/NCT03525678	Ongoing; recruitment complete	A Study to Investigate the Efficacy and Safety of Two Doses of GSK'916 in Subjects With Multiple Myeloma Who Have Failed Prior Treatment With an Anti-CD38 Antibody
DREAMM-3	207495	Planned	A Phase III Open-Label, Randomized Study to Evaluate the Efficacy and Safety of GSK'916 Compared to Pomalidomide plus low-dose Dexamethasone (Pom/Dex) in Participants with Relapsed/Refractory Multiple Myeloma
DREAMM-4	205207/NCT03848845	Recruiting	A Phase I/II Single Arm Open-Label Study to Explore Safety and Clinical Activity of GSK'916 Administered in Combination With Pembrolizumab in Subjects With Relapsed/Refractory Multiple Myeloma
DREAMM-5	208887	Planned	A Phase I/II, Randomized, Open-label Platform Study of GSK'916 with Innovative Combination Anti-Cancer Treatments in Participants with Relapsed/Refractory Multiple Myeloma
DREAMM-6	207497/NCT03544281	Recruiting	Evaluate Safety, Tolerability, and Clinical Activity of GSK'916 Administered in Combination With Lenalidomide Plus Dexamethasone (Arm A), or in Combination With Bortezomib Plus Dexamethasone (Arm B) in Subjects With Relapsed/Refractory Multiple Myeloma
DREAMM-7	207503	Planned	

DREAMM-8	207499	Planned	Phase III study of GSK'916, bortezomib, and dexamethasone versus daratumumab, bortezomib, and dexamethasone in participants with relapsed/refractory multiple myeloma A Phase III, Multicenter, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of GSK'916 in Combination with Pomalidomide and Low-Dose Dexamethasone (GSK'916+Pd) versus Pomalidomide plus Bortezomib and Low-Dose Dexamethasone (PVd) in Participants with Relapsed/Refractory Multiple Myeloma
DREAMM-9	209664	Planned	A phase III study of GSK916 + Standard of Care (SOC) vs. SOC in first line transplant ineligible multiple myeloma patients
DREAMM-10	207500	Planned	'916+novel agent vs SOC

GSK2857916 is not currently approved for use anywhere in the world.

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

About GSK

GSK is 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.

[i] https://www.cancer.net/cancer-types/multiple-myeloma/statistics Last accessed December 2018.
[ii]Adam 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

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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: March 21, 2019

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc