

GLAXOSMITHKLINE PLC

Form 6-K

February 05, 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 05 February 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  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

Issued: 05 February 2019, London UK - LSE Announcement

GSK and Merck KGaA, Darmstadt, Germany announce global alliance to jointly develop and commercialise M7824, a novel immunotherapy with potential in multiple difficult-to-treat cancers

Eight high priority immuno-oncology clinical development studies ongoing or expected to commence in 2019, including studies in non-small cell lung and biliary tract cancers

Merck KGaA, Darmstadt, Germany will receive an upfront payment of €300 million (£260 million) and is eligible for potential development milestone payments of up to €500 million (£440 million) triggered by data from the M7824 lung cancer programme, plus future approval and commercial milestones of up to €2.9 billion (£2.5 billion), for a total potential deal value of up to €3.7 billion (£3.2 billion)

GlaxoSmithKline plc (LSE/NYSE: GSK) and Merck KGaA, Darmstadt, Germany today announced that they have entered into a global strategic alliance to jointly develop and commercialise M7824 (bintrafusp alfa\*). M7824 is an investigational bifunctional fusion protein immunotherapy that is currently in clinical development, including potential registration studies, for multiple difficult-to-treat cancers. This includes a Phase II trial to investigate M7824 compared with pembrolizumab as a first-line treatment in patients with PD-L1 expressing advanced non-small cell lung cancer (NSCLC).

M7824 is designed to simultaneously target two immuno-suppressive pathways, transforming growth factor- $\beta$  (TGF- $\beta$ ) trap and an anti-programmed cell death ligand-1 (PD-L1), that are commonly used by cancer cells to evade the immune system. Bifunctional antibodies aim to increase efficacy above and beyond that achieved with individual therapies or combinations of individual therapies.<sup>1</sup> M7824 has the potential to offer new ways to fight difficult-to-treat cancers beyond the established PD-1/PD-L1 class. In addition to use as a single agent, M7824 is also being considered for use in combination with other assets from the pipelines of both companies.

Dr Hal Barron, Chief Scientific Officer and President R&D, GSK, said: "Despite recent medical advances, many patients with difficult-to-treat cancers don't currently benefit from immuno-oncology therapies leaving them with limited treatment options. M7824 brings together two different biological functions in a single molecule and we have observed encouraging clinical results in treating certain cancer patients, particularly those people with non-small cell lung cancer. I'm excited by the potential impact this first-in-class immunotherapy could have on the lives of cancer patients."

Dr Belén Garijo, Member of the Executive Board and CEO Healthcare of Merck KGaA, Darmstadt, Germany said: "Our bifunctional fusion protein M7824 has the potential to bring new answers to patients living with cancer. Together with GSK we aim to drive a paradigm shift in the treatment of cancer as the leader in this novel class of immunotherapies. GSK clearly emerged as the ideal partner due to their strong commitment to oncology, and the complementary talent and capabilities they will bring to our alliance. We now look forward to harnessing the full potential of M7824 across a broad range of cancer indications as we continue to advance our oncology portfolio."

Merck KGaA, Darmstadt, Germany will receive an upfront payment of €300 million (£260 million) and is eligible for potential development milestone payments of up to €500 million (£440 million) triggered by data from the M7824 lung cancer programme. Merck KGaA, Darmstadt, Germany will also be eligible for further payments upon successfully achieving future approval and commercial milestones of up to €2.9 billion (£2.5 billion). The total potential deal value is up to €3.7 billion (£3.2 billion). Both companies will jointly conduct development and commercialisation with all profits and costs from the collaboration being shared equally on a global basis.

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For GSK, this alliance is a further step in the company's priority to strengthen its pharmaceuticals pipeline. This follows the company's recent acquisition of TESARO, an oncology-focused company based in Waltham, Massachusetts. GSK's approach to oncology is focused on innovation in the areas of immuno-oncology, cell therapy, cancer epigenetics and, most recently, genetic medicine.

This alliance reflects Merck KGaA, Darmstadt, Germany's strategic approach to oncology R&D, identifying those opportunities that can progress the company's highly promising clinical stage assets as efficiently and rapidly as possible, whether through internal expertise and capabilities or external collaborations.

With this alliance, both companies have the leadership position in this new class of immunotherapies, specifically leveraging TGF- $\beta$  biology.

\*Bintrafusp alfa is the proposed International Nonproprietary Name (INN) for the bifunctional immunotherapy M7824. Bintrafusp alfa is currently under clinical investigation and not approved for any use anywhere in the world.

About M7824 (also now known as bintrafusp alfa)

M7824 is an investigational bifunctional immunotherapy that is designed to combine a TGF- $\beta$  trap with the anti-PD-L1 mechanism in one fusion protein. M7824 is designed to combine co-localised blocking of the two immuno-suppressive pathways - targeting both pathways aims to control tumour growth by potentially restoring and enhancing anti-tumour responses. M7824 is currently in Phase I studies for solid tumours, as well as a randomised Phase II trial to investigate M7824 compared with pembrolizumab as a first-line treatment in patients with PD-L1 expressing advanced NSCLC. The multicentre, randomised, open-label, controlled study is evaluating the safety and efficacy of M7824 versus pembrolizumab as a monotherapy treatment.

To-date, nearly 700 patients have been treated with M7824 across more than 10 tumour types in Phase I studies. Encouraging data from the ongoing Phase I studies indicates M7824's potential safety and clinical anti-tumour activity across multiple types of difficult-to-treat cancers, including advanced NSCLC, human papillomavirus-associated cancers, biliary tract cancer (BTC) and gastric cancer. In addition, in pre-clinical studies M7824 demonstrated superior anti-tumour activity, compared with anti-PD-L1 alone or with anti-PD-L1 and TGF- $\beta$  trap when co-administered. In total, eight high priority immuno-oncology clinical development studies are ongoing or expected to commence in 2019, including studies in non-small cell lung and biliary tract cancers.

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](http://www.gsk.com).

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and performance materials. Around 51,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From advancing gene editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices - the company is everywhere. In 2017, Merck KGaA, Darmstadt, Germany, generated sales of €15.3 billion in 66 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany operate as EMD Serono in healthcare, MilliporeSigma in life science, and EMD Performance Materials. Since its founding 1668, scientific

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exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.

1. Lan Y, et al. Enhanced preclinical anti-tumour activity of M7824, a bifunctional fusion protein simultaneously targeting PD-L1 and TGF- $\beta$ . Science Translational Medicine. 2018 Jan; 10(424).

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Cautionary statements 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 2017.

Registered in England & Wales:  
No. 3888792

Registered Office:  
980 Great West Road  
Brentford, Middlesex  
TW8 9GS

SIGNATURES

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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: February 05, 2019

By: VICTORIA WHYTE

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Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc