GLAXOSMITHKLINE PLC
Form 6-K
February 07, 2018

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 07 February 2018

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 7 February, 2018, London UK

GSK's meningitis B vaccine Bexsero receives Breakthrough Therapy Designation from US FDA for prevention of Invasive Meningococcal Disease in children 2-10 years of age

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that it has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for its meningitis B vaccine Bexsero [Meningococcal group B Vaccine (rDNA, component, adsorbed)] for the development of the vaccine in the prevention of Invasive Meningococcal Disease (IMD) caused by serogroup B in children 2-10 years of age.

Bexsero is the first vaccine in the world to receive the Breakthrough Therapy Designation (BTD) twice. In 2014, Bexsero received BTD for development in the prevention of IMD in individuals 10-25 years of age and was subsequently granted Accelerated Approval in January 2015.

GSK Vaccines Chief Scientist Rino Rappuoli, who spent more than 20 years developing Bexsero, said: "This designation emphasises the importance of tackling big scientific challenges like meningitis B and breaking new ground in disease prevention through approaches like reverse vaccinology. GSK is committed to the pursuit of innovative vaccines that help protect against serious diseases with significant unmet need."

Breakthrough Therapy Designation is designed to expedite the development and review of drugs and vaccines that are intended to treat or prevent serious conditions and preliminary clinical evidence indicates that the drug or vaccine may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).1 Drugs and vaccines that receive Breakthrough Therapy Designation are eligible for all features of the FDA's Fast Track designation, including more frequent communication with the FDA about the drug's development plan and eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.2

GSK Vaccines Chief Medical Officer Dr Thomas Breuer said: "Thirty-five percent of all meningitis B cases in the US occur in children under 11 years old.3 This designation is an important step forward in meningococcal prevention and extending the protection provided by this vaccine to a vulnerable age group in the US. We look forward to continuing to work with regulators and public health partners to make this vaccine available for them."

About meningococcal serogroup B disease
Invasive meningococcal B disease is the leading cause of life-threatening meningitis in the industrialised world. Although not common, invasive meningococcal B disease develops rapidly, typically amongst previously healthy children and adolescents, and results in high morbidity and mortality. Initial symptoms can often resemble flu, making it difficult to diagnose. About one in 10 of those who contract the disease may die, even with appropriate treatment. Additionally, up to 20 percent of those who survive bacterial meningitis may suffer a major physical or neurological disability (limb loss, hearing loss or seizures).4,5

About Bexsero
Bexsero is licensed in more than 35 countries,6 including the U.S. In the U.S., Bexsero is approved for use in individuals from 10 years through 25 years of age. The countries where Bexsero is licensed include the member states of the European Union and European Economic Area, Australia, Argentina, Chile and Uruguay, where Bexsero is approved for individuals two months of age and older, and in Canada for those aged 2 months to 17 years of age. In Brazil, Bexsero is approved for use in individuals from two months to 50 years of age. To date, GSK has distributed

more than 20 million doses of Bexsero worldwide.

Important safety information
In the US, the vaccine is currently licensed for adolescents (>11 years of age) and adults. The most common local and systemic adverse reactions observed were pain, redness, and swelling, fatigue, headache, and nausea. Bexsero is contraindicated in cases of hypersensitivity (allergy) to any ingredients of the vaccine, or hypersensitivity after a previous dose of Bexsero. Vaccination with Bexsero may not provide protection against all meningococcal serogroup B strains. Vaccination with Bexsero may not result in protection in all vaccine recipients.7

Consult the full Prescribing Information / Summary of Product Characteristics for all labelled safety information for Bexsero. Up-to-date information about GSK prescription medicines may be found at: http://health.gsk.com/.

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/about-us

1 U.S. Food and Drug Administration. Breakthrough Therapy
https://www.fda.gov/forpatients/approvals/fast/ucm405397.htm

2 U.S. Food and Drug Administration. Fast Track

https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm

3CDC Enhanced Meningococcal Disease Surveillance Report (2016)

https://www.cdc.gov/meningococcal/downloads/NCIRD-EMS-Report.pdf

4 World Health Organization. Meningococcal meningitis

http://www.who.int/mediacentre/factsheets/fs141/en/

5 Viner RM, et al. Lancet Neurol. 2012;11:774-783

6 Watson PS, Turner DPJ. Clinical experience with the meningococcal B vaccine, Bexsero®: Prospects for reducing the burden of meningococcal serogroup B disease. Vaccine. 34 (2016) 875-880
http://dx.doi.org/10.1016/j.vaccine.2015.11.05.

7 Bexsero Summary of Product Characteristics https://www.medicines.org.uk/emc/medicine/28407

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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:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
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: February 07, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc