GLAXOSMITHKLINE PLC
Form 6-K
October 27, 2016

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 27 October 2016

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: 27 October, London UK

GSK presents new data for shingles candidate vaccine at IDWeek scientific conference

- New studies support flexible dosing and co-administration with flu vaccine

GSK today announced new data for its shingles candidate vaccine ShingrixTM, at the Infectious Disease Week (IDWeek) scientific conference in New Orleans, Louisiana, USA. The data examined co-administration of GSK's candidate vaccine with the flu vaccine; a flexible dosing schedule; and the vaccine's impact on quality of life.

Summary of new data

Using subjects from two multicentre, multinational studies from the global phase III candidate vaccine clinical programme, ZOE-50 (NCT01165177) and ZOE-70 (NCT01165229), the vaccine's impact on quality of life was analysed. Due to the high efficacy across all ages in these two pivotal trials, only a few subjects in the vaccines arm developed "breakthrough" shingles after vaccination, as expected. Using an established standard health survey, those who had developed shingles reported reduced levels of pain compared to the group that did not receive the vaccine. The study concluded that in addition to helping prevent shingles, the candidate vaccine also reduced the severity of shingles in the few patients who developed the disease after vaccination.

In the phase III clinical trial programme, adults aged 50 years or over received two doses of the candidate vaccine two months apart. A new study (ZOSTER-026) of 354 patients showed that the second dose of the vaccine could be administered during a window of two to six months following the first dose, with a similar level of immune response and comparable safety profile.

A study (ZOSTER-004) conducted during the 2013 Northern Hemisphere flu season with adults aged 50 years or over showed that when the candidate vaccine was given to patients at the same time as an unadjuvanted seasonal flu vaccine, both vaccines were well tolerated and the immune response to each vaccine was similar whether it was administered at the same time or separately.

Across the clinical trial programme, the risk of serious adverse events, potential immune-mediated diseases or deaths observed was similar in people receiving Shingrix and placebo. The most commonly reported local adverse reaction was pain at the injection site and the most frequently reported systemic adverse reaction was fatigue. The majority of injection site and systemic reactions occurred within seven days of vaccination, with most lasting 1-3 days, and generally were mild-to-moderate in intensity.

GSK included data on flexible dosing and co-administration with unadjuvanted seasonal flu vaccine in its regulatory file submission to the United States Food and Drug Administration (FDA) on Monday 24 October 2016. Data will also be part of the licensure applications in other parts of the world, which are planned later this year.

Dr Thomas Breuer, Chief Medical Officer GSK Vaccines said: "Shingles is a common but serious condition that results from the reactivation of the virus that causes chicken pox. The risk of getting shingles increases sharply after 50 years of age. GSK's shingles candidate vaccine has consistently shown high efficacy in older people in its phase III development programme. This underscores the potential impact of this novel vaccine candidate to help prevent shingles, and to help overcome the challenge of decreasing immunity that comes with age. Today's new data further support the vaccine candidate's profile in helping to prevent shingles and improve quality of life, and provide new evidence to support flexible dosing options."

IDWeek is the combined annual meeting of the Infectious Diseases Society of America (IDSA), the Society for Healthcare Epidemiology of America (SHEA), the HIV Medicine Association (HIVMA), and the Pediatric Infectious Diseases Society (PIDS). In addition to presenting data about shingles, GSK will also be presenting abstracts on improving the prevention of influenza through vaccination.

About Shingrix

The candidate vaccine is a non-live, recombinant vaccine to help prevent herpes zoster and its complications and combines glycoprotein E, a protein found on the varicella zoster virus (VZV) that causes shingles, with an adjuvant

system, AS01B, which is intended to enhance the immunological response to the antigen3. GSK intends to register the product as ShingrixTM, subject to approval by relevant regulatory review bodies. The name Shingrix is not yet approved for use by regulatory authorities in any country.

Additional trials to evaluate the ability of the vaccine candidate to help prevent shingles are ongoing in older adults aged 50 and older and in adults with compromised immune systems. These studies will provide additional information with respect to the efficacy and safety profile of the candidate vaccine in an immunocompromised population as well as its ability to stimulate immune responses in other populations and in specific circumstances.

About the phase III study programme
Involving more than 37,000 subjects globally, the phase III programme for GSK's candidate shingles vaccine evaluates its efficacy, safety and immunogenicity. In addition to older adults, the candidate vaccine is being evaluated in immunocompromised patient populations, including solid and haematological cancer patients, haematopoietic stem cell and renal transplant recipients and HIV-infected people.

About the Zoster-026 study
In this study, two doses of the candidate vaccine were administered two, six or 12 months apart. Immune response and safety profile after these alternative dose schedules were compared.

About the Zoster-004 study
In this study, quadrivalent inactivated seasonal influenza vaccine was given at the same time as the first dose of the vaccine candidate, or both vaccines were given sequentially. Immune response and safety profile were compared.

About shingles
Shingles typically presents as a painful, itchy rash that develops on one side of the body, as a result of reactivation of latent chickenpox virus (varicella zoster virus or VZV). Data from many countries indicates that more than 90% of adults have been infected with varicella during childhood. The individual lifetime risk of developing shingles is approximately one in three for people in the USA; however, this increases to one in two people aged 85 and over. A person's risk for shingles increases sharply after 50 years of age due to a natural age-related decline in immune system function, or as a consequence of an underlying immunocompromising condition.4

The most common complication from shingles is post-herpetic neuralgia, defined as localised pain of significant intensity persisting at least 90 days after the appearance of the acute shingles rash. Other complications of shingles include ophthalmologic, neurological and cutaneous disease, which can result in severe disability.5

References
1. Cunningham et al., N Engl J Med 2016; 375: 1019-32. Efficacy of the herpes zoster subunit vaccine in adults 70 years of age or older.
2. Lal et al., N Engl J Med 2015; 372:2087-2096 Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults
3. Shingles (Herpes Zoster) Clinical Overview. US Centers for Disease Control and Prevention. Accessed at: http://www.cdc.gov/shingles/hcp/clinical-overview.html on 6 Sept 2016.
4. Cohen et al., N Engl J Med 2013;369:255-63 Clinical practice: Herpes zoster.
5. The GSK proprietary AS01 adjuvant system contains QS-21 Stimulon® adjuvant licensed from Antigenics LLC, a wholly owned subsidiary of Agenus Inc. (NASDAQ: AGEN), MPL and liposomes

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.

GSK enquiries:			
UK Media enquiries:	David Mawdsley	+44 (0) 20 8047 5502	(London)
	Catherine Hartley	+44 (0) 20 8047 5502	(London)
	Melinda Stubbee	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Sarah Alspach	+1 202 715 1048	(Washington, DC)
	Sarah Spencer	+1 215 751 3335	(Philadelphia)
	Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
	Karen Hagens	+1 919 483 2863	(North Carolina)
	Gwynne Oosterbaan	+1 215 751 7468	(Philadelphia)
Analyst/Investor enquiries:	Tom Curry	+ 1 215 751 5419	(Philadelphia)
	Gary Davies	+44 (0) 20 8047 5503	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)

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 'Risk factors' in the company's Annual Report on Form 20-F for 2015.

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: October 27, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc