GLAXOSMITHKLINE PLC
Form 6-K
October 25, 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 25 October 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

--

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: 25 October 2017, London UK

CDC's Advisory Committee on Immunization Practices recommends Shingrix as the preferred vaccine for the prevention of shingles for adults aged 50 and up

Committee recommends immunization for up to 62 million additional adults in the US

GlaxoSmithKline plc [LSE/NYSE: GSK] today announced that the US Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted in favor of three recommendations for the use of Shingrix (Zoster Vaccine Recombinant, Adjuvanted) for the prevention of shingles (herpes zoster):

Herpes Zoster subunit vaccine (Shingrix) is recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged 50 years and older.

Herpes Zoster subunit vaccine (Shingrix) is recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received Zoster Vaccine Live (Zostavax).

Herpes Zoster subunit vaccine (Shingrix) is preferred over Zoster Vaccine Live (Zostavax) for the prevention of herpes zoster and related complications.

The new recommendations mean up to 62 million more adults in the US should be immunized, approximately 42 million aged 50-59 years old and 20 million who have previously been vaccinated against shingles.[1]

Dr. Thomas Breuer, Senior Vice President and Chief Medical Officer of GSK Vaccines said:
"After the age of 50, a person's risk for shingles increases. As our immune system ages, all of us become more vulnerable to shingles.[2] GSK developed Shingrix specifically to overcome the age-related decline in immunity. Today's vote is an important step forward for the prevention of shingles, as the expanded recommendation will bring access to a vaccine with efficacy of greater than 90%, which will help protect more American adults from a painful and serious condition."

Shingrix was approved by the US Food and Drug Administration (FDA) on October 20, 2017 for use in adults aged 50 years and older. Data from studies of people vaccinated with Shingrix, who were previously vaccinated with Zostavax, have been presented previously to the ACIP and have been published in peer-reviewed journals, but have not yet been reviewed by the FDA.[3],[4]

Patrick Desbiens, Senior Vice President, US Vaccines said: "We believe these recommendations reflect the promise of Shingrix and the role this vaccine can play in reducing the incidence and burden of shingles. Only 31% of adults over the age of 60 have been immunized against shingles and we look forward to partnering with public health officials, healthcare professionals and payers as these recommendations are implemented.1"

Approval of Shingrix was based on a comprehensive Phase III clinical trial program involving 38,000 adults to evaluate the vaccine's efficacy, safety and immunogenicity. In a pooled analysis of these studies, Shingrix demonstrated efficacy against shingles greater than 90% across all age groups, as well as sustained efficacy over a follow-up period of 4 years.[5],[6] By preventing shingles, Shingrix also reduced the overall incidence of postherpetic neuralgia (PHN), a form of chronic nerve pain lasting from at least three months up to several years and the most common complication associated with shingles.1

The most common side effects of Shingrix are pain, redness, and swelling at the injection site, muscle pain, tiredness, headache, shivering, fever, and upset stomach, which are related to the immune system responding to the vaccine. Based on available data, the majority of reactions to the vaccine were transient and mild to moderate in intensity, lasting less than three days.

The ACIP recommendations will be forwarded to the director of the CDC and the US Department of Health and Human Services for review and approval. Once approved, the final recommendations will be published in a future Morbidity and Mortality Weekly Report (MMWR).

About shingles

Shingles is caused by the reactivation of the varicella zoster virus (VZV), the same virus that causes chickenpox.2 Nearly all older adults have the VZV dormant in their nervous system, waiting to reactivate with advancing age.[7] As people age, the cells in the immune system lose the ability to maintain a strong and effective response to VZV reactivation.2,[8]

Shingles typically presents as a painful, itchy rash that develops on one side of the body and can last for two to four weeks. The pain associated with shingles is often described as burning, shooting or stabbing.5,8 Even once the rash is gone, a person can experience postherpetic neuralgia (PHN), pain lasting from at least three months up to several years.2 PHN is the most common complication of shingles, occurring in 10 to 18 percent of all shingles cases.2,[9]

There are an estimated 1 million cases of shingles in the United States each year.2 More than 99 percent of those over 50 years old are infected with VZV and one in three Americans will develop shingles in their lifetime. The risk increases to one in two for adults aged 85 years and older.2,[10]

About SHINGRIX

Shingrix is a non-live, recombinant subunit vaccine approved in the United States and Canada to help prevent shingles (herpes zoster) in people aged 50 years or older. It combines an antigen, glycoprotein E, and an adjuvant system, AS01B, intended to generate a strong and long-lasting immune response that can help overcome the decline in immunity as people age.[11]

Full US Prescribing Information is available at
https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Shingrix/pdf/SHINGRIX.P

Important Safety Information for Shingrix

You should not receive Shingrix if you are allergic to any of its ingredients or had an allergic reaction to a previous dose of Shingrix.

The most common side effects are pain, redness, and swelling at the injection site, muscle pain, tiredness, headache, shivering, fever, and upset stomach.

Vaccination with Shingrix may not protect all individuals.

Ask your healthcare provider about the risks and benefits of Shingrix. Only a healthcare provider can decide if Shingrix is right for you.

Shingrix is not indicated for the prevention of chickenpox.

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:	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Sarah Spencer	+1 215 751 3335	(Philadelphia)
	Gwynne Oosterbaan	+1 215 751 7468	(Philadelphia)
	Sean Clements	+1 215 347 9274	(Philadelphia)
Analyst/Investor enquiries:	Sarah Elton-Farr	+44 (0) 20 8047 5194	(London)
	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 'Principal risks and uncertainties' in the company's Annual Report on Form 20-F for 2016.

[1] Dooling K. Considerations for the use of herpes zoster vaccine. Presented at the Advisory Committee on Immunization Practices, US Centers for Disease Control and Prevention. October 25, 2017.
[2] Harpaz R, Ortega-Sanchez IR, Seward JF; Advisory Committee on Immunization Practices (ACIP), Centers for Disease Control and Prevention (CDC). Prevention of herpes zoster: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2008 Jun;57(RR-5):1-30.
[3] Colindres R. Immunogenicity and Safety of Shingrix in Adults Previously Vaccinated With a Live-Attenuated Herpes Zoster Vaccine (Zoster-048 Study). Presented at the Advisory Committee on Immunization Practices, US Centers for Disease Control and Prevention. June 21, 2017.
[4] Grupping K et al. Immunogenicity and Safety of the HZ/su Adjuvanted Herpes Zoster Subunit Vaccine in Adults Previously Vaccinated with a Live-Attenuated Herpes Zoster Vaccine. J Infect Dis. 2017; doi: 10.1093/infdis/jix482.
[5] Lal H et al. Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults. N Engl J Med. 2015;372:2087-96.
[6] Cunningham et al. Efficacy of the herpes zoster subunit vaccine in adults 70 years of age or older. N Engl J Med. 2016;375:1019-32.
[7] Gnann et al. Clinical practice. Herpes zoster. N Eng J Med. 2002;347(5):340-6.
[8] Johnson RW et al. Herpes zoster epidemiology, management, and disease and economic burden in Europe: a multidisciplinary perspective. Therapeutic Advances in Vaccines. 2015;3(4):109-120.
[9] Yawn et al. Health care utilization and cost burden of herpes zoster in a community population. Mayo Clin Proc. 2009;84(9):787-94.
[10] Cohen et al. Herpes Zoster. N Eng J Med. 2013;369:255-63.

[11] 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.

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 25, 2017

By: VICTORIA WHYTE

Victoria Whyte

Authorised Signatory for and on

behalf of GlaxoSmithKline plc