GLAXOSMITHKLINE PLC
Form 6-K
October 23, 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 23 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

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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: 20 October 2017, London UK

Shingrix approved in the US for prevention of shingles in adults aged 50 and over

Pooled clinical trial results showed > 90 percent efficacy across all age groups

GlaxoSmithKline plc [LSE/NYSE: GSK] today announced that the US Food and Drug Administration (FDA) has approved Shingrix (Zoster Vaccine Recombinant, Adjuvanted) for the prevention of shingles (herpes zoster) in adults aged 50 years and older. Shingrix is a non-live, recombinant subunit vaccine given intramuscularly in two doses.

Dr. Thomas Breuer, Senior Vice President and Chief Medical Officer of GSK Vaccines said: "Shingrix represents a significant scientific advancement in the field of vaccinology. The vaccine has shown over 90% efficacy across all age groups in the prevention of shingles, a painful and potentially serious disease that affects 1 in 3 people in the United States.1 The risk and severity of shingles increases with age as the immune system loses the ability to mount a strong and effective response to infection. Shingrix was developed specifically to overcome the age-related decline in immunity."

Approval of Shingrix is based on a comprehensive Phase III clinical trial program evaluating its efficacy, safety and immunogenicity in more than 38,000 people. 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.2,3 By preventing shingles, Shingrix also reduced the overall incidence of postherpetic neuralgia (PHN), a form of chronic nerve pain and the most common complication associated with shingles.

Luc Debruyne, President of Global Vaccines at GSK said: "We believe Shingrix will provide confidence in the protection one can expect from a shingles vaccine. GSK is committed to partnering with the public health and medical community to help address the gaps in vaccine coverage among adults that persist in the United States."

The US Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) is expected to vote on a recommendation for the use of Shingrix at its meeting on 25 October 2017.

Following this approval from FDA, and pending a recommendation from ACIP, Shingrix will be available shortly.

On 13 October 2017, Shingrix was approved in Canada for the prevention of shingles (herpes zoster) in people aged 50 years or older. Regulatory filings in the European Union, Australia and Japan are underway.

About shingles

Shingles is caused by the reactivation of the varicella zoster virus (VZV), the same virus that causes chickenpox.1 Nearly all older adults have the VZV dormant in their nervous system, waiting to reactivate with advancing age.4 As people age, the cells in the immune system lose the ability to maintain a strong and effective response to VZV reactivation.1,5,

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. 2,5 Even once the rash is gone, a person can experience postherpetic neuralgia (PHN), pain lasting from at least three months up to several years.1 PHN is the most common complication of shingles, occurring in 10 to 18 percent of all shingles cases.1,6,

There are an estimated 1 million cases of shingles in the United States each year.1 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.1,7,

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.8

Full US Prescribing Information will be available soon at www.us.gsk.com. Prior to the label being posted online, a copy of the label may be requested from one of the GSK Media or Investor Relations contacts listed in the "GSK Enquiries" section at the end of this document.

Shingrix Important Safety Information

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.

Inside Information
The information contained in this announcement is inside information.

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.

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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
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TW8 9GS

1 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.
2 Lal H et al. Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults. N Engl J Med. 2015;372:2087-96.
3 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.
4 Gnann et al. Clinical practice. Herpes zoster. N Eng J Med. 2002;347(5):340-6.
5 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.
6 Yawn et al. Health care utilization and cost burden of herpes zoster in a community population. Mayo Clin Proc. 2009;84(9):787-94.
7 Cohen et al. Herpes Zoster. N Eng J Med. 2013;369:255-63.
8 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 23, 2017

By: VICTORIA WHYTE----------

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc