GLAXOSMITHKLINE PLC
Form 6-K
January 26, 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 26 January 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: 26 January 2018, London UK

GSK's Shingrix receives positive opinion from the CHMP in Europe for the prevention of shingles in adults aged 50 and over

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending marketing authorisation for Shingrix for the prevention of shingles (herpes zoster) and post-herpetic neuralgia (PHN), the most common and often painful shingles-related complication, in adults aged 50 years or older.[i] Shingrix is a non-live, recombinant subunit adjuvanted vaccine given intramuscularly in two doses, with a two-to-six month interval between doses.

Shingles is caused by reactivation of the varicella zoster virus, the same virus that causes chickenpox.[ii] A person's risk for shingles increases sharply after 50 years of age. Nearly all adults over 50 have the shingles virus dormant in their nervous system, waiting to reactivate with advancing age.

Dr. Thomas Breuer, Senior Vice President and Chief Medical Officer of GSK Vaccines said: "Shingles is a painful and potentially serious condition. The risk of developing shingles increases with age and it is estimated that around one in three people will develop shingles in their lifetime. Shingrix is specifically designed to overcome the age-related weakening of the immune system and is an important step forward in the prevention of shingles."

Shingrix is the first shingles vaccine to combine a non-live antigen, to trigger a targeted immune response, with a specifically designed adjuvant to generate a strong and sustained immune response.

A CHMP positive opinion is one of the final steps before Marketing Authorisation is granted by the European Commission. A final decision by the European Commission is anticipated in April 2018.

Shingrix was approved in Canada and the US in October 2017 and has been recommended by the US Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices for the prevention of herpes zoster and related complications for immunocompetent adults aged 50 years and older. Regulatory reviews of the vaccine are currently underway in Australia and Japan.

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

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.[vi] Even once the rash is gone, a person can experience post-herpetic neuralgia (PHN), pain lasting from at least three months up to several years. PHN is the most common complication of shingles, occurring in up to 30 percent of all shingles cases. [vii]

Shingles affects approximately 1.7 million Europeans annually[viii]. Older adults and those with conditions that compromise the immune system have the greatest risk for developing shingles. More than 99 percent of those over 50 years old are infected with VZVix and, it is estimated that around one in three people will develop shingles in their lifetime.x

About Shingrix

Shingrix [Herpes Zoster vaccine (non-live recombinant, AS01B adjuvanted)] is a non-live, recombinant subunit vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older. The vaccine 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.[x]i

Shingrix is to be given intramuscularly in two doses with a two-to-six month interval between doses.

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 professional about the risks and benefits of Shingrix. Only a healthcare professional 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.

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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

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Brentford, Middlesex
TW8 9GS

[i]http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/01/news_detail_002888.jsp&mid=WC0b
[ii] 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
[iii] Harpaz et al. 2008
[iv] Gnann et al. Clinical practice. Herpes zoster. N Eng J Med. 2002;347(5):340-6.
[v] Harpaz et al. 2008; 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.
[vi] Gnann et al. 2002; 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.
[vii] Kawei K et al., BMJ Open 2014;4(6):e004833
[viii] Pinchinat et al. Similar herpes zoster incidence across Europe: results from a systematic literature review. BMC Infectious Diseases 2013, 13:170
[ix] Kilgore et al J Med Virol. 2003;70 Suppl 1:S111-8
X Harpaz et al. 2008; Brissson et al. Epidemiology of varicella zoster virus infection in Canada and the United Kingdom. Epidemiol. Infect. (2001), 127, 305±314.
[x]i 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: January 26, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc