GLAXOSMITHKLINE PLC
Form 6-K
October 13, 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 13 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: Friday 13 October 2017, London UK

GSK announces first approval of Shingrix in Canada

The only shingles vaccine to achieve ≥90% efficacy in adults aged 50 and over

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that Shingrix has been approved in Canada for the prevention of shingles (herpes zoster) in people aged 50 years or older.[i] Shingrix is a non-live, recombinant subunit adjuvanted vaccine given intramuscularly in two 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. Up to one in three Canadians will develop shingles in their lifetime.[iii],[iv],[v]

"One of the biggest challenges in vaccine research is to create vaccines that are effective in older adults who are at greater risk for certain diseases, like shingles. As we age, our immune system loses the ability to mount a strong and effective response to infection[vi]. Shingrix was developed specifically to overcome the age-related decline in immunity against the varicella zoster virus," said Dr Thomas Breuer, Senior Vice President and Chief Medical Officer of GSK Vaccines.

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.

The approval of Shingrix in Canada, the first received worldwide, was based on a comprehensive phase III clinical trial programme evaluating its efficacy, safety and immunogenicity in more than 37,000 people.[vii] In a pooled analysis of these studies the vaccine demonstrated efficacy against shingles greater than 90%, independent of age (≥50, ≥70 years of age), as well as sustained efficacy over the entire follow-up period of four years.[viii],[ix] The most common side effects reported in the clinical trials were pain, redness and swelling at the injection site. Based on available data, the majority of reactions to the vaccine were transient and mild to moderate in intensity, lasting less than three days.vi,vii

GSK's global clinical trial programme for the vaccine includes involvement of 31 trial sites and over 2,100 participants across Canada.

Dr Susie Barnes, Vice President and Country Medical Director, GSK Canada, said: "We're very pleased to provide Shingrix as a new option to help protect Canadians 50 years and older against shingles. Shingles is a common and potentially serious condition with approximately 130,000 new cases each year in Canada. It can cause lasting pain and other complications which can severely impact the quality of people's lives."

Regulatory reviews of Shingrix are underway in the US, EU, Australia and Japan.

About Shingrix
Shingrix [Herpes Zoster vaccine (non-live recombinant, AS01B adjuvanted)] is a non-live, recombinant subunit vaccine to help prevent herpes zoster (shingles) 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]

Shingrix is to be given intramuscularly in two doses with a two-to-six month interval between doses. The Product Monograph, posted at www.ca.gsk.com, should be consulted for complete administration and safety information. Prior to being posted online, the Product Monograph is also available by calling 1-800-387-7374.

About shingles
Shingles is caused by varicella zoster virus (VZV), the same virus that causes chickenpox.[xi] Nearly all older adults have the VZV dormant in their nervous system, waiting to reactivate with advancing age.[xii] As people age, the immune system loses the ability to mount a strong and effective response to infection.[xiii]

Shingles typically presents as a rash, with painful blisters across the chest, abdomen or face. The pain is often described as aching, burning, stabbing or shock-like. Following the rash, a person can also experience post-herpetic neuralgia (PHN), pain that can last for months or years x PHN is the most common complication of shingles, occurring in up to 30 percent of all shingles cases.[xiv]

Shingles affects approximately 130,000 Canadians annually.[xv] Incidence rates are similar throughout North America, Europe and Asia-Pacific regions.xiii Older adults and those with conditions that compromise the immune system have the greatest risk for developing shingles. More than 90 percent of those over 50 years old are infected with VZV and one in three will develop shingles in their lifetime. The risk increases to one in two for adults aged 85 years and older.x

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 statements
GSK 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

[i] SHINGRIX Canadian Product Mongraph
[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] National Advisory Committee on Immunization (NACI). Statement on the Recommended use of Herpes Zoster Vaccine. January 2010, 36(ASC-1):1-19.
[iv] Brisson, M, et al. Modelling the impact of immunization on the epidemiology of varicella zoster virus. Epidemiol. Infect. 2000; 125, 651-669
[v] CIG, 2014 Canadian Immunization Guide, accessed August 15, 2017.
http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/4-canadian-immunization-guide-canadien-immunisation/ind
[vi] . Black S et al. Sci Transl Med. 2015.
[vii] GlaxoSmithKline. Data on File. 2017.
[viii] Lal H, et al., Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults. N Engl J Med, 2015;372:2087-96.
[ix] Cunningham AL, Lal H, Kovac M, Chlibek R, Hwang S-J, Diez-Domingo J, et al. Efficacy of the herpes zoster subunit vaccine in adults 70 years of age or older. N Engl J Med. 2016 Sep;375(11):1019-32.
[x] 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.
[xi] Harpaz, et al. MMWR Recomm Rep. 2008; 57(5): 1-30. Prevention of herpes zoster: recommendations of the Advisory Committee on Immunization Practices.
[xii] Gnann, et al. N Eng J Med. 2002; 347(5): 340-6. Clinical practice. Herpes zoster.
[xiii] Gruver, et al. J Pathol. 2007: 211(2): 144-56. Immunosenescence of ageing.
[xiv] Kawai, et al. BMJ Open. 2014; 4(6). Systematic review of incidence and complications of herpes zoster: towards a global perspective.

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 13, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc