GLAXOSMITHKLINE PLC
Form 6-K
October 24, 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 24 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

--

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: 24 October 2016, London UK - LSE Announcement

GSK announces US regulatory submission of candidate vaccine for prevention of shingles
- Regulatory submissions in the EU and Canada remain on track for 2016

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that it has submitted a Biologics License Application (BLA) for its candidate shingles vaccine, ShingrixTM, to the United States Food and Drug Administration (FDA), seeking approval for the prevention of herpes zoster (shingles) in people aged 50 years or over.

The candidate vaccine is a non-live, recombinant vaccine to help prevent shingles and its complications. The phase III clinical trial programme showed that by reducing the incidence of shingles, the candidate vaccine also reduced the overall incidence of postherpetic neuralgia (PHN), a form of chronic pain associated with shingles. Regulatory approval is being sought for the vaccine to be given intramuscularly in two doses, with a two to six month interval between doses.

Dr Emmanuel Hanon, Senior Vice President and Head of Vaccines R&D, GSK said: "Shingles is a common and potentially serious condition. It can cause lasting pain and other complications such as scarring or visual impairment, which can severely impact the quality of people's lives. The risk of developing shingles increases with age and it is estimated that up to one in every three people is at risk. Today's file submission puts us a step closer to making this vaccine available to help protect more people from shingles and the complications associated with it."

The regulatory submission for Shingrix is based on a comprehensive phase III clinical trial programme evaluating its efficacy, safety and immunogenicity in more than 37,000 people. This includes the ZOE-50 and ZOE-70 studies published in the New England Journal of Medicine in April 2015 and September 2016, respectively.1,2

The candidate vaccine is one of the more than 40 assets profiled to investors at GSK's R&D event in November 2015 and belongs to the company's vaccines portfolio - one of six core areas of scientific research and development alongside oncology, immuno-inflammation, and infectious, respiratory and rare diseases.

Regulatory submissions in the European Union and Canada are on track for 2016 and planned for Japan in 2017. GSK's shingles candidate vaccine is not currently approved for use anywhere in the world.

About the phase III study programme
Involving more than 37,000 subjects globally, the phase III programme evaluated the efficacy, safety and immunogenicity of two doses of GSK's candidate shingles vaccine given intramuscularly two months apart in older adults. Data from all the completed studies has been included in the regulatory file:

The ZOE-50 (ZOster Efficacy in adults aged 50 years and over) (NCT01165177) trial of 16,160 adults aged 50 years and older studied overall vaccine efficacy against shingles compared to placebo. The data were published in April 2015 in the NEJM.1

The ZOE-70 (ZOster Efficacy in adults aged 70 years and over) (NCT01165229) trial of more than 14,800 adults aged 70 years and older studied overall vaccine efficacy against shingles compared to placebo. Additionally, a pooled analysis of data from the ZOE-70 and ZOE-50 trials assessed overall vaccine efficacy in reducing the risk of developing shingles and PHN in people aged 70 years and over. These data were published in September 2016 in the NEJM. 2

A clinical study is also underway to evaluate revaccination in subjects who have previously been vaccinated against shingles with the currently available live-attenuated vaccine. Additional trials are underway in solid and haematological cancer patients, haematopoietic stem cell and renal transplant recipients and HIV-infected people. These studies will provide additional information on the candidate vaccine's safety and ability to stimulate immune responses in populations at high risk of shingles because of the weakening of their immune system.

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 has been approved by the European Medicines Agency.

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 a 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. Lal et al., N Engl J Med 2015; 372:2087-2096 Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults.
2. 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.
3. 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.
4. 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.
5. Cohen et al., N Engl J Med 2013;369:255-63 Clinical practice: Herpes zoster.

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 24, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc