GLAXOSMITHKLINE PLC
Form 6-K
April 28, 2015

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 April 2015

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

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Issued: Tuesday 28 April 2015, London UK, LSE Announcement

GSK candidate vaccine for the prevention of shingles demonstrates overall efficacy of 97.2% which does not diminish in the age groups studied

- Shingles is a significant public health burden, more than 90 per cent of adults aged 50 years and over are at risk[i],[ii],vi

GlaxoSmithKline plc (LSE/NYSE: GSK) today presented detailed data from a randomised phase III study of its investigational vaccine candidate for the prevention of shingles, HZ/su, showing vaccine efficacy was maintained across age groups, from 50 years to 70 years and over. The data was presented at the 25th Scientific Congress of the European Society of Clinical Microbiology and Infectious diseases (ECCMID) in Copenhagen and published online simultaneously in the New England Journal of Medicine.

Analysis of the primary endpoint showed that a two-dose schedule of HZ/su reduced the risk of herpes zoster by 97.2% (95% confidence interval [CI] 93.7-99.0) in adults aged 50 years and older compared to placebo. Vaccine efficacy was maintained across the various age groups included in the study, ranging between 96.6% in people aged 50-59 years, 97.4% in those aged 60-69 years, 97.6% in people aged 60 years and above, and 98% in those 70 years or older. There was no significant difference in vaccine efficacy among the age groups.

The proportions of subjects with serious adverse events, potential immune-mediated diseases, or deaths were similar in vaccine and placebo groups. The most commonly reported local adverse reaction was pain with the others being redness and swelling at the injection site. These were graded severe in 9.5% of HZ/su recipients compared to 0.4% of placebo recipients. The more frequently reported systemic adverse reactions were muscle pain, fatigue and headache, of which 11.4% were graded severe in the HZ/su group compared to. 2.4% in the placebo group. These reactions mostly occurred within 7 days of vaccination with most lasting 1-3 days.

The HZ/su candidate vaccine is non-live and combines gE, a protein found on the virus that causes shingles, with an adjuvant system, AS01B,[iii] which is intended to enhance the immunological response to gE.

Additional trials to evaluate the ability of HZ/su to prevent shingles are ongoing in people aged 70 and older and in adults with compromised immune systems. These studies will provide additional information with respects to the safety of HZ/su and its ability to stimulate immune responses in specific populations. These studies will also address the degree to which HZ/su can prevent complications of shingles, such as chronic neuropathic pain, also known as post-herpetic neuralgia (PHN).[iv]

Dr Moncef Slaoui, Chairman Global Vaccines at GSK, said: "We are extremely encouraged that the results may point out a health benefit in the prevention of shingles. This disease can be painful and potentially debilitating for some people and older people are particularly at risk. We look forward to continuing the development of our Zoster programme"

Notes to editors

About the ZOE-50 trial

The ZOE-50 (Zoster efficacy in adults aged 50 years and over))study is a randomised, observer-blind, placebo-controlled (saline solution) multicentre, multinational (North America, Europe, Latin America, Asia-Pacific) phase III trial involving 16,160 adults aged 50 years and older. The study started in August 2010 and reported headline efficacy data in December 2014. Doses were given intramuscularly on a 2-dose schedule at 0 and 2 months. The primary endpoint of this study is the overall vaccine efficacy (VE) of the candidate vaccine HZ/su across all age

cohorts compared to placebo in reducing the risk of developing shingles. The study includes subjects in the age ranges 50-59, 60-69, 70-79, and ³80 years.

About the phase III HZ/su study programme

Involving more than 37,000 subjects globally, the phase III programme for candidate vaccine HZ/su will evaluate its efficacy, safety and immunogenicity. In addition to older adults, HZ/su is being evaluated in immunocompromised patient populations, including solid and haematological cancer patients, haematopoietic stem cell and renal transplant recipients and HIV-infected people.

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, VZV). Anyone who has been infected with VZV is at risk of developing shingles, with age and altered immune system being recognised as the main risk factors.vi Complications from shingles can include PHN, (the most common complication).iv, scarring, vision complications, secondary infection and nerve palsies.

Data from many countries indicate that older adults (aged 50 and over) are at risk of Herpes zoster since more than 90 per cent have been infected with wild type VZV ,[v], . A person's risk for shingles increases sharply after 50 years of age. Risk of complications, including PHN and hospitalisation, also increase with age. The individual lifetime risk of developing HZ is approximately one in three people; however, for individuals aged 85 and over, this risk increases to one in two people.[vi]

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 'Risk factors' in the company's Annual Report on Form 20-F for 2014.

References

[i] Shingles (Herpes Zoster) Clinical Overview. US Centers for Disease Control and Prevention, May 1st 2014. Accessed at: http://www.cdc.gov/shingles/hcp/clinical-overview.html on 15th April 2015.

[ii] Sadzot-Delvaux, et al., 2008; JID (suppl). 197:S185

The GSK proprietary AS01 adjuvant system contains QS-21 Stimulon® adjuvant licensed from Antigenics Inc, a wholly owned subsidiary of Agenus Inc. (NASDAQ: AGEN), MPL and liposomes

Johnson, RW et al N Engl J Med 2014;371:1526-33

[v] Shingles (Herpes Zoster) Clinical Overview. US Centers for Disease Control and Prevention, May 1st 2014. Accessed at: http://www.cdc.gov/shingles/hcp/clinical-overview.html on 15th April 2015.

[vi] S. Pinchinat et al: Similar herpes zoster incidence across Europe: results from a systematic literature review. BMC Infectious Diseases 2013, 13:170

Registered in England & Wales:
No. 3888792

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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: April 28, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc