GLAXOSMITHKLINE PLC
Form 6-K
October 27, 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 October 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 27 October 2015, London UK - LSE Announcement

GSK's candidate shingles vaccine demonstrates 90% efficacy against shingles in people 70 years of age and over

- Candidate vaccine also demonstrates efficacy of 89% against postherpetic neuralgia (PHN), a painful complication of shingles
- File submission is anticipated second half of 2016

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that the second pivotal phase III study of its candidate vaccine Shingrix™ in adults aged 70 years and over (known as ZOE-70) successfully met its primary objective, demonstrating 90% (95% confidence interval: 84-94) efficacy against shingles compared to placebo. The high efficacy seen in ZOE-70 is in line with the efficacy shown in the first pivotal phase III study in adults aged 50 years and over (ZOE-50) presented earlier this year i.

In addition, a pre-specified pooled analysis of ZOE-70 and ZOE-50 data demonstrated that the candidate vaccine effectively prevents subsequent chronic neuropathic pain, also known as postherpetic neuralgia (PHN) which is the most common severe complication of shingles. Shingrix was demonstrated to be 89% (95% confidence interval: 69-97) efficacious in preventing PHN in people aged 70 years and over and 91% (95% confidence interval: 76- 98) efficacious in people aged 50 years and over.

Based on these and the previously reported ZOE-50 data, GSK intends to submit a regulatory application for Shingrix for the prevention of shingles in people 50 years of age and over in North America, in Japan and EU during the second half of 2016.

Alain Brecx, MD, Vaccine Development Leader at GSK said: "Together, these remarkable results underscore the potential of the candidate vaccine to prevent both shingles and PHN in older adults. About 90% of people 50 years and over are at risk of developing shingles, a painful disease that negatively impacts peoples' health and quality of life. I would like to thank all the people who participated in the two ZOE studies and the clinical investigators."

The risk for shingles and for complications (including PHN) increases as of 50 years of age. GSK's candidate shingles vaccine is a non-live vaccine and combines gE, a protein found on the virus that causes shingles with an adjuvant system, AS01B ii, which enhances the immunological response to gE.

The full set of safety data from the ZOE-70 trial is currently being analysed and will be disclosed in the coming months. The Independent Data Monitoring Committee (IDMC) for the ZOE-70 study, in its ongoing review of the safety data up to April 2015, did not raise any concerns. The safety profile of the candidate vaccine in older adults is based on data from more than 16,000 subjects who received the vaccine in phase I, II and III clinical trials (including ZOE-50 and 70). The most common adverse events seen in the seven days after vaccination from these studies included local symptoms (pain, redness, swelling at the injection site) and systemic symptoms (muscle pain, fatigue and headache). Data from the study are expected to be presented at a forthcoming scientific conference and submitted for publication in a peer-reviewed journal.

Notes to editors
The name Shingrix™ is not approved for use by any regulatory authority, including the US Food and Drug Administration (FDA) or European Medicines Agency (EMA).

About the ZOE-70 trial

The ZOE-70 (ZOster Efficacy in adults aged 70 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 more than 14,800 adults aged 70 years and older. Two doses were given intramuscularly two months apart. The study, which started in August 2010 in parallel with the ZOE-50 trial, includes subjects in the age ranges 70-79 and ≥80 years. The primary objective of ZOE-70 is overall vaccine efficacy across people 70 years and over, compared to placebo in reducing the risk of shingles. The co-primary objectives are the assessment of overall vaccine efficacy in reducing the risk of developing shingles and PHN in people aged 70 years and over using the pooled shingles and PHN cases from both ZOE-70 and ZOE-50 studies.

The most common severe complication of shingles is PHN iii, which is defined as a localized pain of significant intensity persisting at least 90 days after the appearance of the acute shingles rash.

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 more than 16,000 adults aged 50 years and over. The study started in August 2010 and reported headline efficacy data in December 2014. Two doses were given intramuscularly two months apart. The primary objective of this study is the overall vaccine efficacy of the candidate vaccine across all age cohorts compared to placebo in reducing the risk of developing shingles. The results of ZOE-50 were reported in the NEJM in April 2015 i.

About the phase III study programme
Involving more than 37,000 subjects globally, the phase III programme for the candidate vaccine evaluates its efficacy, safety and immunogenicity. In addition to older adults, the candidate vaccine is being evaluated in immunocompromised patient populations, including solid organ and haematological cancer patients and haematopoietic stem cell and renal transplant recipients.

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 iii. Complications from shingles can include PHN, (the most common severe complication occurring in 15% to 30% of shingles cases) 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 shingles since about 90% have been infected with wild type VZV i. A person's risk for shingles increases as of 50 years of age. Risk of complications, including PHN also increases 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 v.

Shingrix™ is a trade mark of the GSK group of companies

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. Lal H, Cunningham AL, Godeaux O, Chlibek R, Diez-Domingo J, Hwang SJ, Levin MJ, McElhaney JE, Poder A, Puig-Barberà J, Vesikari T, Watanabe D, Weckx L, Zahaf T, Heineman TC; ZOE-50 Study Group.. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. N Engl J Med. 2015;372:2087-96
ii. The GSK proprietary AS01 adjuvant system contains QS-21 adjuvant licensed from Antigenics Inc, a wholly owned subsidiary of Agenus Inc. (NASDAQ: AGEN), MPL and liposomes
iii. Shingles (Herpes Zoster) Clinical Overview. US Centers for Disease Control and Prevention, May 1st 2014. Accessed at: www.cdc.gov/shingles/hcp/clinical-overview.html on 15th April 2015.
iv. Dworkin RH, O'Connor AB, Backonja M, Farrar JT, Finnerup NB, Jensen TS, Kalso EA, Loeser JD, Miaskowski C, Nurmikko TJ, Portenoy RK, Rice AS, Stacey BR, Treede RD, Turk DC, Wallace MS. Pharmacologic management of neuropathic pain: evidence-based recommendations. Pain. 2007 Dec 5;132(3):237-51. Epub 2007 Oct 24. Review.
v. Pinchinat et al: Similar herpes zoster incidence across Europe: results from a systematic literature review. BMC Infectious Diseases 2013, 13:170

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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 27, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc