GSK announces positive pivotal phase III data for 5-in-1 Meningococcal ABCWY vaccine candidate

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For media and investors only

MenABCWY combination vaccine candidate met all its primary endpoints of the pivotal phase III clinical trial and was well tolerated with a safety profile consistent with Bexsero and Menveo

The primary endpoint data demonstrated statistical non-inferiority compared to Bexsero and Menveo in individuals 10-25 years old, with the 5-in-1 vaccine candidate eliciting a clinically meaningful immune response

If approved, this 5-in-1 vaccine candidate could provide the broadest meningococcal serogroup coverage and could lead to a simplified immunisation schedule

GSK plc (LSE/NYSE: GSK) today announced positive headline results from the phase III trial (NCT04502693) evaluating the safety, tolerability, and immunogenicity of its MenABCWY combination vaccine candidate, administered as two doses given six months apart in healthy individuals aged 10-25 years. GSK's MenABCWY vaccine candidate combines the antigenic components of its licensed meningococcal vaccines, Bexsero (MenB) and Menveo (MenACWY). All primary endpoints were met, including the non-inferiority of the vaccine candidate for all five Neisseria meningitides serogroups (A, B, C, W, and Y) compared to licensed meningococcal vaccines Bexsero and Menveo in terms of an immune response. In addition, the vaccine candidate was well tolerated, with a safety profile consistent with Bexsero and Menveo.

Invasive meningococcal disease (IMD), a major cause of meningitis and septicaemia, is an uncommon but serious illness that can cause

life-threatening complications or even death, typically amongst previously healthy children and adolescents. 1 Among those contracting meningococcal diseases, one in ten will die, sometimes in as little as 24 hours, despite treatment. 2 One-in-five survivors suffers long-term consequences, such as brain damage, amputations, hearing loss and nervous system problems. 1

Five Neisseria meningitides serogroups (A, B, C, W, and Y) account for nearly all IMD cases in most of the world. 3 As yet, no licensed combination vaccine offers protection against these serogroups in a single vaccine. Currently, in the US, two separate vaccines needing four injections are required to protect against all five serogroups. This immunisation regimen, coupled with low awareness of the disease, can lead to sub-optimal immunisation coverage rates, particularly for MenB, with an estimated coverage of only approximately 31% of adolescents in the US. 4

Tony Wood, Chief Scientific Officer at GSK, said:

> These statistically significant phase III data are a very encouraging step toward reducing the incidence of meningococcal disease. In the US, routine use of a 5-in-1 meningococcal vaccine with a two-dose regimen in adolescents at 16 to 18 years of age, just before this disease's incidence peak, could drive significant public health impact. In addition, our 5-in-1 meningococcal vaccine candidate builds on our global leadership in meningococcal vaccines and commitment to innovation.

GSK is working closely with regulators to review the full phase III data set, including the supplemental Biologics License Application for Bexsero. This clinical trial was both the confirmatory trial for Bexsero and the phase III trial for MenABCWY. Detailed results from this phase III trial will be presented in a peer-reviewed publication and at upcoming scientific meetings.

Editor's note: This press release was originally published on 14 March 2023 and has been updated for comprehensiveness on 11 May 2023.

About the MenABCWY phase III trial

The trial conducted by GSK is a phase III randomised, controlled, observer-blind, multi-country trial to evaluate the safety, tolerability,

and immunogenicity of GSK's MenABCWY vaccine candidate. It is part of a comprehensive programme to generate clinical evidence on the benefits of meningococcal immunisation. The trial started in August 2020, and approximately 3,650 participants aged 10-25 were enrolled in the US, Canada, Czech Republic, Estonia, Finland, Turkey, and Australia.

The objective of the trial was to assess the safety profile of the MenABCWY vaccine candidate and to compare the immune responses of the trial's participants who received two doses of the MenABCWY vaccine candidate six months apart to the responses of those in the control groups who received GSK's licensed vaccines, Bexsero (MenB) and Menveo (MenACWY). There are a total of 11 primary endpoints for the trial, five for MenABCWY and six for Bexsero. Bexsero is used as the comparator for the MenB immune responses induced by the MenABCWY vaccine in the trial, which is both the phase III trial for MenABCWY and confirmatory trial for Bexsero.

Bexsero is currently licensed or has received regulatory approval in over 50 countries, including the US and EU, and is used in 13 national immunisation programmes worldwide for the prevention of IMD caused by Neisseria meningitides serogroup B. Bexsero is the only MenB vaccine with trials that have demonstrated a reduction in IMD, including vaccine effectiveness in real-world settings. Regulatory approvals vary by country. It is approved for individuals two months of age and older in Europe.

In the US, Bexsero is licensed under the Accelerated Approval pathway for active immunisation to prevent IMD caused by Neisseria meningitides serogroup B in individuals from 10 through 25 years. Approval of Bexsero is based on demonstrating an immune response, as measured by serum bactericidal activity against three serogroup B strains representative of prevalent strains in the US. The effectiveness of Bexsero against diverse serogroup B strains has not been confirmed. The US Prescribing Information is available here (PDF - 327KB).

Menveo vaccine for meningococcal groups A, C, Y, and W has received regulatory approval in over 60 countries, including the US, with more than 72 million doses distributed worldwide since 2010. Menveo offers extensive evidence of immunogenicity with a well-

characterised safety profile (consistent with similar vaccines).

In the US, Menveo has received regulatory approval for active immunisation to prevent IMD caused by Neisseria meningitides serogroups A, C, Y, and W in individuals from 2 months through 55 years of age. However, Menveo does not prevent N. meningitides serogroup B infections. The US Prescribing Information is available here (PDF - 556KB).

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com/company

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 2022, GSK’s Q4 Results for 2022 and any impacts of the COVID-19 pandemic.

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