GSK presents pivotal data at ESPID confirming effectiveness of its 5-in-1 meningococcal ABCWY vaccine candidate, with demonstrated coverage against a panel of 110 MenB strains

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For media and investors only

- Preliminary results from phase III trial show all primary endpoints met, demonstrating statistical non-inferiority compared to Bexsero (meningococcal group B vaccine) and Menveo (meningococcal group A, C, W-135, and Y conjugate vaccine), in individuals 10-25 years old with an acceptable safety profile

- Only investigational 5-in-1 vaccine with demonstrated immunological effectiveness against 110 diverse MenB invasive strains in a clinical trial

- If approved, this vaccine candidate could provide the broadest coverage against the most prevalent meningococcal serogroups and could lead to a simplified immunisation schedule

GSK plc (LSE/NYSE: GSK) today presented preliminary positive results from the phase III trial (NCT04502693) evaluating the immunological vaccine effectiveness and safety of its MenABCWY combination vaccine candidate, administered as two doses given six months apart in healthy individuals aged 10-25 years. The preliminary data were disclosed at the 41st Annual Meeting of the European Society for Paediatric Infectious Diseases (ESPID) in Lisbon, Portugal.

The vaccine candidate demonstrated non-inferiority in primary endpoints for five Neisseria meningitidis serogroups (A, B, C, W, and Y) compared to two doses of Bexsero (meningococcal group B

vaccine) and one dose of Menveo (meningococcal group A, C, W-135, and Y conjugate vaccine) in 10–25-year-olds. In addition, the vaccine candidate was generally well tolerated, with a safety profile consistent with Bexsero and Menveo. In a separate confirmatory arm of this phase III trial, the MenABCWY vaccine candidate showed immunological effectiveness against a panel of 110 diverse meningococcal serogroup B (MenB) invasive strains, which account for 95% of strains circulating in the US. 1

Tony Wood, Chief Scientific Officer at GSK, said:

> These preliminary data further unlock the potential of our MenABCWY vaccine candidate in providing protection against invasive meningococcal disease caused by serogroups A, B, C, W and Y. It's particularly encouraging to see the breadth of coverage against the broadest panel of circulating MenB strains to date, as we know MenB is the most common cause of meningococcal disease in the US with the lowest immunisation rate.

Five Neisseria meningitidis serogroups (A, B, C, W, and Y) account for nearly all invasive meningococcal disease (IMD) cases in most of the world. 2 Meningitis B is the most common serogroup in the US and accounts for more than half of meningococcal disease cases among 16–20-year-olds. 3, 4 Currently immunisation coverage rates for Men B are estimated at approximately 31% of adolescents in the US. 5 GSK's MenABCWY vaccine candidate combines the antigenic components of licensed meningococcal vaccines, Bexsero and Menveo. The aim of combining two effective vaccines into one is to help simplify immunisation schedules, which can in turn increase vaccination coverage and help reduce the overall burden of disease.

Professor Terry Nolan, principal investigator for the phase III trial, and Head of the Vaccine and Immunisation Research Group at the Peter Doherty Institute for Infection and Immunity at the University of Melbourne, and Murdoch Children's Research Institute, said:

> Meningococcal vaccination can help save lives and these results are significant in moving one step closer to protection against five meningococcal serogroups with a single vaccine. The potential for a simplified immunisation schedule could improve accessibility for the target population susceptible to meningococcal disease.

GSK is working closely with regulatory agencies to review the full phase III data set, including the supplemental Biologics License Application for Bexsero for confirmation of full licensure under the Accelerated Approval pathway. Detailed results will be submitted for publication in a peer-reviewed scientific journal later this year.

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, to assess the immunological vaccine effectiveness against a panel of 110 MenB strains, 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 one dose of 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 in the US.

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 meningitidis 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 meningitidis 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.

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

About Invasive meningococcal disease

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. 6 Among those contracting meningococcal diseases, one in ten will die, sometimes in as little as 24 hours, despite treatment. 7 One-in-five survivors suffer long-term consequences, such as brain damage, amputations, hearing loss and nervous system problems. 6

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.

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 2022, GSK's Q1 Results for 2023 and any impacts of the COVID-19

pandemic.

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