Stock-exchange announcement
For media and investors only

Issued: February 14, 2025, Philadelphia

PENMENVY, GSK's 5-in-1 meningococcal vaccine, approved by US FDA to help protect against MenABCWY

- Vaccine helps protect against five common disease-causing serogroups of *Neisseria meningitidis* (A, B, C, W, and Y)
- Broad serogroup coverage in one vaccine reduces injections to help improve vaccination rates and help protect more US adolescents and young adults

---

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved PENMENVY (Meningococcal Groups A, B, C, W, and Y Vaccine) for use in individuals aged 10 through 25 years. The vaccine targets five major serogroups of *Neisseria meningitidis* (A, B, C, W, and Y) which commonly cause invasive meningococcal disease (IMD).[1,2]

The vaccine combines the antigenic components of GSK's two well-established meningococcal vaccines, BEXSERO (Meningococcal Group B Vaccine) and MENVEO (Meningococcal [Groups A, C, Y, and W-135] Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine). The regulatory application was supported by positive results from two phase III trials [NCT04502693; NCT04707391], which evaluated the vaccine's safety, tolerability, and immune response in over 4,800 participants aged 10-25 years. The safety data demonstrated that the vaccine has a safety profile consistent with GSK's licensed meningococcal vaccines.[3-5]

Tony Wood, Chief Scientific Officer, GSK, said: "We are excited about the opportunities ahead to help improve meningococcal vaccination coverage in the United States, especially for IMD caused by serogroup B. Building on our global leadership in meningococcal vaccination and our longstanding commitment to address unmet need in disease prevention, we aim to help protect more teens and young adults at a life stage when they are at an increased risk."

Integrating GSK's MenABCWY vaccine into healthcare provider practices could simplify meningococcal vaccination delivery and help protect more US adolescents against these five common disease-causing serogroups – A, B, C, W, and Y – for which the US Centers for Disease Control and Prevention (CDC) have issued recommendations.[6] Although MenB is the leading cause of IMD among this population, less than 13% receive the recommended two-dose vaccination series; around 32% receive at least one dose.[7,8] Three of every four MenB doses currently administered in the US are manufactured by GSK,[9] positioning the company well to lead in the US market as MenB-containing vaccinations must be completed with the same manufacturer's MenB vaccine.

Judy Klein, President and Founder of Unity Consortium, a non-profit organization focused on adolescent health and immunization in the US, said: "The consequences of IMD can be devastating for those who contract it, for their families and friends. We welcome new tools to help protect more adolescents from meningococcal disease. Pentavalent MenABCWY vaccines could help address the disease by providing protection against the five vaccine-preventable serogroups in one vaccine and making it easier for adolescents to get the coverage they need."

At its meeting on February 26, 2025, the CDC's Advisory Committee on Immunization Practices (ACIP) is expected to vote on recommendations for the appropriate use of GSK's MenABCWY vaccine in adolescents and young adults.

About IMD
IMD is an uncommon but serious illness that can lead to death for up to one in six of those who contract it in as little as 24 hours from onset, despite treatment.[10,11] IMD is easily misdiagnosed, with early symptoms often mistaken for the flu.[11,12] Approximately one in five survivors may experience long-term consequences such as brain damage, amputations, hearing loss, and nervous system problems.[10,12] Although anyone can get IMD, adolescents and young

adults between the ages of 16 and 23 years are one of the groups at highest risk due to common behaviors that help

transmit the bacteria that cause IMD such as living in close quarters like college dormitories, kissing and sharing drinks, utensils, or smoking devices.[13,14]

About PENMENVY (Meningococcal Groups A, B, C, W, and Y Vaccine)
GSK's MenABCWY vaccine is an injectable suspension for intramuscular use. The vaccine is supplied as one vial of lyophilized MenACWY Component (powder) which is reconstituted at the time of use with the accompanying prefilled syringe of MenB Component (liquid). It is indicated in the US for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y. It is approved in the US for use in individuals aged 10 through 25 years. The US Prescribing Information is available here.[15]

Important Safety Information for PENMENVY in the US
The following is based on the US Prescribing Information for PENMENVY. Please consult the full Prescribing Information for additional safety information.

- Do not administer PENMENVY to individuals with a severe allergic reaction (e.g., anaphylaxis) to a previous dose of PENMENVY, to any component of this vaccine, or to any other diphtheria toxoid-containing vaccine
- Syncope (fainting) has occurred in association with administration of PENMENVY
- PENMENVY may not protect all vaccine recipients and may not provide protection against all meningococcal serogroup B strains
- Immunocompromised persons, including those receiving immunosuppressive therapy, may have reduced immune responses to PENMENVY
- Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation are at increased risk for invasive disease caused by *N. meningitidis,* including disease caused by serogroups A, B, C, W, and Y, even if they develop antibodies following vaccination with PENMENVY
- Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of a U.S.-licensed meningococcal quadrivalent polysaccharide conjugate vaccine. The decision by the healthcare professional to administer PENMENVY to persons with a history of GBS should take into account the expected benefits and potential risks
- The most commonly reported solicited adverse reactions in individuals aged 10 through 25 years after Dose 1 and Dose 2: pain at the injection site, fatigue, headache, myalgia, nausea, erythema, and swelling. The most commonly reported solicited adverse reactions in MenACWY conjugate vaccine-experienced individuals aged 15 through 25 years after Dose 1 and Dose 2: pain at the injection site, headache, fatigue, myalgia, and nausea

About BEXSERO (Meningococcal Group B Vaccine)
GSK's MenB vaccine has received regulatory approval in over 55 countries, including the US, and is used in 18 national immunization programs worldwide for the prevention of IMD caused by *Neisseria meningitidis* serogroup B. More than 110 million doses have been distributed worldwide since 2015.[16] It is supported by clinical data supporting its effectiveness in helping to protect adolescents and young adults against diverse disease-causing strains of MenB, with a well-characterized safety profile. In the US, this vaccine has received regulatory approval for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B and is approved for use in individuals aged 10 through 25 years. The US Prescribing Information is available here.[17]

Important Safety Information for BEXSERO in the US
The following is based on the US Prescribing Information for BEXSERO. Please consult the full Prescribing Information for additional safety information.

- Do not administer BEXSERO to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of BEXSERO or after a previous dose of BEXSERO
- The tip cap of the prefilled syringe may or may not be made with natural rubber latex. Natural rubber latex may cause allergic reactions
- Syncope (fainting) can occur in association with administration of BEXSERO
- BEXSERO may not protect all vaccine recipients and may not provide protection against all meningococcal serogroup B strains
- Some individuals with altered immunocompetence may have reduced immune responses to BEXSERO
- Individuals with certain complement deficiencies and individuals receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by *N. meningitidis* serogroup B even after being vaccinated with BEXSERO
- The most commonly reported solicited adverse reactions: pain at the injection site, fatigue, headache, nausea, erythema, myalgia, and swelling

About MENVEO (Meningococcal [Groups A, C, Y, and W-135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine)
GSK's MenACWY vaccine has received regulatory approval in over 60 countries, including the US, with more than 80 million doses distributed worldwide since 2010.[18] It offers evidence of immunogenicity with a well-characterized safety profile. In the US, this vaccine has received regulatory approval for active immunization to prevent IMD caused by *Neisseria meningitidis* serogroups A, C, Y, and W in individuals from 2 months through 55 years of age. MENVEO does not prevent *N. meningitidis* serogroup B infections. The US Prescribing Information is available here.[19]

Important Safety Information for MENVEO in the US
The following is based on the US Prescribing Information for MENVEO. Please consult the full Prescribing Information for additional safety information

- Do not administer MENVEO to individuals with a severe allergic reaction (e.g., anaphylaxis) to a previous dose of MENVEO, to any component of this vaccine, or to any other diphtheria toxoid-containing vaccine
- Syncope (fainting) has occurred in association with administration of MENVEO
- Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to MENVEO
- Individuals with certain complement deficiencies and individuals receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W, even after being vaccinated with MENVEO
- Guillain-Barré syndrome has been reported in temporal relationship following administration of another US-licensed meningococcal quadrivalent polysaccharide conjugate vaccine
- Apnea following intramuscular vaccination has been observed in some infants born prematurely
- Common solicited adverse reactions: at 2 months of age - tenderness and erythema at injection site, irritability, sleepiness, persistent crying, change in eating habits, vomiting, and diarrhea; at 7 months through 23 months of age - tenderness and erythema at injection site, irritability, sleepiness, persistent crying, change in eating habits, and diarrhea; at 2 through 10 years of age - injection site pain, erythema, irritability, induration, sleepiness, malaise, and headache. Among adolescents and adults aged 11 through 55 years were pain at the injection site, headache, myalgia, malaise, and nausea - similar rates were observed following a booster dose
- In two clinical studies, there were no notable differences in frequency and severity of solicited adverse reactions in individuals who received MENVEO 1-vial presentation compared to individuals who received the 2-vial presentation
- Vaccination with MENVEO may not result in protection in all vaccine recipients

About GSK
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.

GSK enquiries

Media:	Simon Moore / Dan Smith / Sarah Clements	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Lyndsay Meyer	+1 202 302 4595	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Annabel Brownrigg-Gleeson	+44 (0) 7901 101944	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Camilla Campbell	+44 (0) 7803 050238	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)

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 GSK's Annual Report on Form 20-F for 2023, and GSK's Q4 Results for 2024.

Registered in England & Wales:
No. 3888792

Registered Office:
79 New Oxford Street
London
WC1A 1DG

References:

1. Centers for Disease Control and Prevention. *About Meningococcal Disease*. Available at: https://www.cdc.gov/meningococcal/about/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmeningococcal%2Fabout%2Fcauses-transmission.html. Accessed February 2025.
2. European Centers for Disease Control and Prevention. *Factsheet about meningococcal disease*. Available at: https://www.ecdc.europa.eu/en/meningococcal-disease/factsheet. Accessed February 2025.
3. GSK. *GSK's 5-in-1 meningococcal ABCWY vaccine candidate accepted for regulatory review by US FDA*. Available at: https://www.gsk.com/en-gb/media/press-releases/gsk-s-5-in-1-meningococcal-abcwy-vaccine-candidate-accepted-for-regulatory-review-by-us-fda/. Accessed February 2025.
4. NIH. *Effectiveness of GlaxoSmithKline Biologicals S.A.'s Meningococcal Group B and Combined ABCWY Vaccines in Healthy Adolescents and Young Adults*, ClinicalTrials.gov. Available at: https://clinicaltrials.gov/study/NCT04502693. Accessed February 2025.
5. NIH. *Immunogenicity and Safety Study of GSK's MenABCWY Vaccine in Healthy Adolescents and Adults Previously Primed With MenACWY Vaccine*, ClinicalTrials.gov. Available at: https://www.clinicaltrials.gov/study/NCT04707391. Accessed February 2025.
6. Centers for Disease Control and Prevention. *Meningococcal Vaccine Recommendations*. Available at: https://www.cdc.gov/meningococcal/hcp/vaccine-recommendations/index.html. Accessed February 2025.
7. Cheng WY, et al. Determinants of Meningococcal ACWY vaccination in adolescents in the US: completion and compliance with the CDC recommendations. *Hum Vaccin Immunother*. 2020;16(1):176-188.
8. Centers for Disease Control and Prevention. *National Vaccination Coverage Among Adolescents Aged 13–17 Years — National Immunization Survey-Teen, United States, 2023*. Available at: https://www.cdc.gov/mmwr/volumes/73/wr/mm7333a1.htm#:~:text=Among%20adolescents%20aged%2013%E2%80%9317%20years%20included%20in%20the%202023,view%2Fcdc%2F159388). Accessed February 2025.
9. Based on information licensed from IQVIA: IQVIA, DDD, Meningococcal B market all channels, period January – December 2024, reflecting estimates of real-world activity. All rights reserved.
10. World Health Organisation. *Meningitis fact sheet*. Available at: https://www.who.int/news-room/fact-sheets/detail/meningitis. Accessed April 2024.
11. Thompson MJ, et al. Clinical recognition of meningococcal disease in children and adolescents. *Lancet*. 2006;367(9508):397-403.
12. Marshall GS, et al. Understanding the Sequelae of Invasive Meningococcal Disease in the United States. *Infect Dis Ther*. 2024;13(11):2213-2220.
13. European Centers for Disease Control and Prevention. *Outbreak of invasive meningococcal disease in the EU associated with a mass gathering event, the 23rd World Scout Jamboree, in Japan*. 21 August 2015. Available at: https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/Meningococcal-disease-scouts-EU-August-2015.pdf. Accessed February 2025.
14. Centers for Disease Control and Prevention. *Risk Factors for Meningococcal Disease*. Available at: https://www.cdc.gov/meningococcal/risk-factors/index.html. Accessed February 2025.
15. GSK. US Prescribing Information for *Penmenvy*. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Penmenvy/pdf/PENMENVY.PDF. Accessed February 2025.
16. GSK Data on File. *Number of Bexsero doses shipped from 2015 to November 2023* REF-219766
17. GSK. US Prescribing Information for *Bexsero*. Available at: gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Bexsero/pdf/BEXSERO.PDF. Accessed February 2025.
18. GSK Data on File. *Menveo Doses Shipped from 2010 to end of 2022* REF-195452
19. GSK. Prescribing Information for *Menveo*. Available at: gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Menveo/pdf/MENVEO.PDF. Accessed February 2025.