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GSK's 5-in-1 meningococcal vaccine PENMENVY receives positive recommendation from US Advisory Committee on Immunization Practices

- Vaccine recommended to help protect persons over 10 years old in the United States (US) against 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
- Vaccine doses will be ready for use in the US from Summer 2025

GSK plc (LSE/NYSE: GSK) today announced that the US Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) has voted to recommend use of PENMENVY (Meningococcal Groups A, B, C, W, and Y Vaccine) as part of the adolescent meningococcal vaccination schedule. Recommendations made by the ACIP are reviewed and, if adopted, are published as official CDC recommendations.

ACIP voted to recommend that persons over 10 years old receive a single dose of PENMENVY as an alternative to separate administration of meningococcal serogroups A, C, W, and Y (MenACWY) and meningococcal serogroup B (MenB) vaccinations when both vaccines would be given on the same clinic visit, typically at age 16. This recommendation, if adopted, will allow for vaccination against serogroups A, B, C, W, and Y in fewer doses, could simplify meningococcal vaccination delivery and could improve immunization rates, helping protect more US adolescents against these five disease-causing serogroups for which the US CDC has previously issued recommendations.¹

GSK's MenABCWY vaccine combines the antigenic components of the Company's two well-established meningococcal vaccines—BEXSERO (Meningococcal Group B Vaccine) and MENVEO (Meningococcal [Groups A, C, Y, and W-135] Oligosaccharide Diphtheria CRM₁₉₇ Conjugate Vaccine). On February 14, 2025, the US Food and Drug Administration (FDA) [approved](#) GSK's MenABCWY vaccine for use in individuals aged 10 through 25 years.²

Tony Wood, Chief Scientific Officer at GSK, said: "We welcome this positive recommendation that can help strengthen disease prevention efforts in the US. Pentavalent vaccines can reduce the number of injections required to help protect against invasive meningococcal disease – especially disease caused by serogroup B. Their use could improve immunization rates among adolescents and young adults in the US, who are at an age with increased risk."

Although MenB is the leading cause of invasive meningococcal disease (IMD) among this population, less than 13% of 17-year-olds received the recommended two-dose vaccination series; around 32% received at least one dose according to 2023 CDC survey data.^{3,4} Three of every four MenB doses currently administered in the US are manufactured by GSK,⁵ positioning the company well to lead in the US market as MenB-containing vaccination schedules must be completed with the same manufacturer's MenB vaccine.⁶

About IMD

IMD is an uncommon but serious illness that can lead to death for up to one in ten of those who contract it in as little as 24 hours from onset, despite treatment.⁷ IMD is easily misdiagnosed, with early symptoms often mistaken for the flu.^{7,8} Approximately one in five survivors may experience long-term consequences such as brain damage, amputations, hearing loss, and nervous system problems.⁸ 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

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drinks, utensils, or smoking devices.^{9,10}

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). In the US, PENMENVY is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y in individuals aged 10 through 25 years. The FDA-approved dosing is to administer two doses six months apart. The US Prescribing Information is available [here](#).¹¹

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 2015.¹² Clinical data supported 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, BEXSERO is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B in individuals aged 10 through 25 years. The US Prescribing Information is available [here](#).¹³

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

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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 2010.¹⁴ It offers evidence of immunogenicity with a well-characterized safety profile. In the US, MENVEO is indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135 in individuals 2 months through 55 years of age. MENVEO does not prevent *N. meningitidis* serogroup B infections. The US Prescribing Information is available [here](#).¹⁵

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.

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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 in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024.

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