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Issued: April 16, 2024, Philadelphia, PA

GSK's 5-in-1 meningococcal ABCWY vaccine candidate accepted for regulatory review by US FDA

- Vaccine candidate could provide broad coverage against the five most common groups of bacteria causing invasive meningococcal disease and reduce number of injections to simplify immunization, if approved
- PDUFA goal date for decision set by FDA for February 14, 2025
- Submission based on results from pivotal phase III trial showing all primary endpoints met

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has accepted for review a Biologics License Application (BLA) for its 5-in-1 meningococcal ABCWY (MenABCWY) vaccine candidate. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the US FDA on this application is February 14, 2025.

GSK's 5-in-1 MenABCWY vaccine candidate combines the antigenic components of its two well-established meningococcal vaccines with demonstrated efficacy and safety profiles, BEXSERO (Meningococcal Group B Vaccine) and MENVEO (Meningococcal [Groups A, C, Y, and W-135] Oligosaccharide Diphtheria CRM₁₉₇ Conjugate Vaccine). The MenABCWY combination will target the five groups of the bacteria *Neisseria meningitidis* (Men A, B, C, W, and Y) that cause most invasive meningococcal disease (IMD) cases globally.¹

Combining the protection offered by these vaccines into fewer shots aims to reduce the number of injections, simplifying immunization. This can help increase series completion and vaccination coverage and help reduce the overall burden of IMD, with unvaccinated adolescents being at particular risk of infection and potential outbreaks.^{2,3,4}

IMD is an unpredictable but serious illness that can cause life-threatening complications.⁵ Despite treatment, among those who contract IMD one in six will die, sometimes in as little as 24 hours.^{6,7} One in five survivors may suffer long-term consequences such as brain damage, amputations, hearing loss and nervous system problems.⁸ Although anyone can get IMD, those who are in their late teens and early adulthood are amongst the groups at higher risk of contracting it.^{9,10}

In the US, while meningococcal vaccine recommendations for all five serogroups have been in place since 2015, annual immunization rates for IMD have remained low overall, due in part to a complex schedule.¹¹ MenB is the most common group of IMD-causing bacteria in US adolescents and young adults, accounting for more than half of the IMD cases among this age group in the US from 2017-2021.¹² For protection against MenB, which is subject to the shared clinical decision-making recommendation of the CDC, just under 12% of US adolescents have had the two required doses.¹⁰

In the phase III trial (NCT04502693), all primary endpoints were achieved for the MenABCWY vaccine candidate, including immunological non-inferiority to one dose of GSK's Meningococcal Groups A,C,Y and W Vaccine, and non-inferior immune responses against 110 diverse MenB invasive strains (representing 95% of MenB strains circulating in the US) as compared to two doses of GSK's Meningococcal Group B Vaccine. The vaccine was well tolerated with a safety profile consistent with both vaccines.¹³

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About the MenABCWY phase III trial

The trial conducted by GSK was a phase III randomised, controlled, observer-blind, multi-country trial to evaluate the safety, tolerability and immunogenicity of GSK's MenABCWY vaccine candidate. 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 demonstrate non-inferiority of 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: two doses of Meningococcal Group B Vaccine and one dose of Meningococcal Groups A,C,Y and W Vaccine.

About BEXSERO

BEXSERO is currently licensed or has received regulatory approval in over 50 countries, including the US and EU, and is used in 16 national immunization programs worldwide for the prevention of IMD caused by *Neisseria meningitidis* serogroup B. In the US, it is licensed under the Accelerated Approval pathway for active immunization to prevent IMD caused by *Neisseria meningitidis* serogroup B in individuals from 10 through 25 years.

In the US, BEXSERO is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B in individuals from 10 through 25 years. Approval of BEXSERO is based on demonstration of 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 at:

https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/BEXSERO/pdf/BEXSERO.PDF

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 all of the labelled safety information.

- BEXSERO is contraindicated in cases of hypersensitivity, including severe allergic reaction, to any component of the vaccine, 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.
- The most common solicited adverse reactions: pain at the injection site, myalgia, erythema, fatigue, headache, induration, nausea, and arthralgia
- Vaccination with BEXSERO 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
- Vaccination with BEXSERO may not result in protection in all vaccine recipients

About MENVEO

MENVEO has received regulatory approval in over 60 countries, including the US, with more than 72 million doses distributed worldwide since 2010. It offers extensive evidence of immunogenicity with a well-characterised 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.

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The US Prescribing Information is available at:

https://gskpro.com/content/dam/global/hcportal/en_US/Prescribing_Information/MENVEO/pdf/MENVEO.PDF

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 all of the labelled safety information.

- Do not administer MENVEO to individuals with a severe allergic reaction (eg, 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 under Item 3.D "Risk factors" in the company's Annual Report on Form 20-F for 2022, and Q4 Results for 2023.

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