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

- Vaccine candidate provides broad coverage against the five most common groups of bacteria causing invasive meningococcal disease and could reduce number of injections to simplify immunisation, if approved
- Prescription Drug User Fee Act action date set by FDA for 14 February 2025
- Submission based on results from pivotal phase III trial showing all primary endpoints met

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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) action date for a regulatory decision by the US FDA on this application is 14 February 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 CRM_{197} 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 immunisation. 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 immunisation 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]

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 55 countries, including the US and EU, and is used in 16 national immunisation programmes 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 immunisation to prevent IMD caused by *Neisseria meningitidis* serogroup B in individuals from 10 through 25 years. As required under the FDA's Accelerated Approval regulations, GSK has completed a confirmatory trial of this vaccine and submitted a supplemental Biologics License Application (sBLA) to convert the accelerated approval to full approval. The US Prescribing Information is available here.[14]

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, this vaccine 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. The US Prescribing Information is available here.[15]

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 2023.

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