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GSK's *Menveo* meningococcal vaccine in new single-vial, fully liquid presentation receives positive European CHMP opinion

- If approved, the fully liquid presentation will offer healthcare providers an option that does not require reconstitution of *Menveo* (MenACWY vaccine) before use
- Marketing authorisation in EU expected by November 2024
- Over 6 million doses of GSK's MenACWY vaccine have been distributed to European countries since 2017 to help protect against invasive meningococcal disease[1]

GSK plc (LSE/NYSE: GSK) today announced that the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended for use a single-vial, fully liquid presentation of *Menveo* (Meningococcal Group A, C, W-135 and Y conjugate vaccine, MenACWY vaccine) to help protect against invasive meningococcal disease (IMD) caused by bacterial groups A, C, W, and Y.

If approved, this single-vial presentation will be licenced for active immunisation of children from 2 years of age, adolescents and adults, offering healthcare providers an option that does not require reconstitution before its use.

Philip Dormitzer, GSK Head of Global Vaccines Research & Development, said: "As a global leader in meningococcal vaccines, we are committed to finding innovative solutions that simplify immunisation against bacterial meningitis, support vaccine uptake and help protect as many people as possible from this devastating disease. We will continue our efforts to help prevent this disease in at-risk populations in the European Union."

GSK's submission to the EMA is based on two positive Phase IIb trials (2017-003692-61; 2017-003456-23).[2,3] The primary and secondary outcomes of these trials, supported by post-hoc pooled analyses, show that the fully liquid formulation of this vaccine has comparable immunogenicity, tolerability and a comparable safety profile to the existing lyophilized/liquid formulation. Today's positive opinion marks one of the final steps prior to the potential extension of the marketing authorisation by the European Commission (EC). The EC's final decision is expected by November 2024.

IMD is an unpredictable but serious illness that can cause life-threatening complications.[4] Despite treatment, among those who contract IMD one in six will die, sometimes in as little as 24 hours.[4] One in five survivors may suffer long-term consequences such as brain damage, amputations, hearing loss and nervous system problems.[4] Although anyone can get IMD, babies, young children and those who are in their late teens and early adulthood are amongst the groups at higher risk.[4]

The original presentation of *Menveo* that requires reconstitution and which was approved by the EMA in 2010 is unaffected by this recommendation.[5]

About *Menveo*
GSK's MenACWY vaccine has received regulatory approval in over 60 countries, with more than 82 million doses distributed worldwide since 2010.[6,7] Over 6 million doses have been distributed to European countries since 2017.[1] It offers evidence of immunogenicity with a well-characterised safety profile.[8,9] In the European Union (EU), this

vaccine has received regulatory approval for active immunisation to prevent IMD caused by *Neisseria meningitidis* serogroups A, C, Y, and W in children from 2 years of age, adolescents and adults.[10] EMA Prescribing Information for *Menveo* can be accessed at: https://www.ema.europa.eu/en/medicines/human/EPAR/menveo

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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1 Data on file: *Menveo doses distributed in Europe from 2017 to August 31st 2024* REF-246217
2 EU Clinical Trials Register, *A phase 2b, randomized, controlled, observer-blind, multi-center, non-inferiority immunogenicity and safety study of two formulations of GSK Biologicals' Meningococcal ACWY conjugate vaccine (GSK3536820A and Menveo) administered to healthy adults 18 to 40 years of age.* Available at: https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-003692-61/results. Accessed September 2024.
3 EU Clinical Trials Register, *A phase 2b, randomized, controlled, observer-blind, multi-center study to evaluate safety and immunogenicity of different formulations of GSK Biologicals' Meningococcal ACWY conjugate vaccine (GSK3536820A and Menveo) administered to healthy adolescents and young adults 10 to 40 years of age..* Available at: https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-003456-23/results. Accessed September 2024.

4 World Health Organization (WHO), *Meningitis Factsheet*, 2023. Available at: https://www.who.int/news-room/fact-sheets/detail/meningitis. Accessed September 2024.
5 EC Decision C(2010)1795 of 16 March 2010 and subsequent amendments; marketing authorisation numbers EU/1/10/614/002 & EU/1/10/614/003
6 Data on File; *List of countries where Menveo is registered and/or commercialized* REF-194949
7 Data on File: *Menveo doses distributed from 2010 to end of 2022* REF-195452
8 Becerra-Culqui TA, Sy LS, Ackerson BK, et al. *Safety of quadrivalent meningococcal conjugate vaccine in infants and toddlers 2 to 23-months old.* Vaccine. 2020; *38*(2), 228–234.
9 Khatami A, Snape MD, Davis E, et al. *Persistence of the immune response at 5 years of age following infant immunisation with investigational quadrivalent MenACWY conjugate vaccine formulations*. Vaccine. 2012; 30:2831–2838. 10.1016/j.vaccine.2012.02.04
10 EMA, *Menveo : EPAR - Product Information – Summary of Product Characteristics.* Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/menveo. Accessed September 2024.