Stock-exchange announcement
For media and investors only

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GSK's fully liquid *Menveo* meningococcal vaccine approved by European Commission

- New fully liquid presentation means reconstitution is not needed before use
- Formulation supports simplification of vaccination process against invasive meningococcal disease (IMD)
- IMD is an unpredictable but serious illness that can cause life-threatening complications

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GSK plc (LSE/NYSE: GSK) today announced that the European Commission (EC) has approved 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 serogroups A, C, W and Y.

This single-vial presentation is now 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 leader in meningococcal vaccines, GSK is dedicated to finding innovative solutions that simplify immunisation and support vaccine uptake. We remain committed to safeguarding individuals from bacterial meningitis, and we will persist in our efforts to prevent this devastating disease among at-risk populations in the European Union."

GSK's submission to the EC was based on two positive Phase IIb trials (2017-003692-61; 2017-003456-23).[1,2] 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 lyophilised/liquid formulation.

IMD is an unpredictable but serious illness that can cause life-threatening complications.[3] Despite treatment, among those who contract IMD up to one in six will die, sometimes in as little as 24 hours.[4,5] One in five survivors may suffer long-term consequences such as neurological damage[6], 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.[7]

The original presentation of *Menveo* that requires reconstitution, and which was approved by the EMA in 2010, is unaffected by this marketing authorisation.[8]

About *Menveo*

GSK's MenACWY vaccine has received regulatory approval in over 60 countries.[9] It offers evidence of immunogenicity with a well-characterised safety profile.[10,11] 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.[12] EMA Prescribing Information for *Menveo* can be accessed at: https://www.ema.europa.eu/en/medicines/human/EPAR/menveo.[12] More than 82 million doses of this vaccine have been distributed worldwide since 2010;[13] over 6 million doses have been distributed to European countries since 2017.[14]

About GSK

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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 GSK's Annual Report on Form 20-F for 2023, and GSK's Q3 Results for 2024.

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[1] 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.

[2] 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.

[3] European Centre for Disease Prevention and Control (ECDC), Factsheet about Meningococcal Disease, 2023. Available at: https://www.ecdc.europa.eu/en/meningococcal-disease/factsheet. Accessed November 2024.

[4] Thompson MJ;Lancet;2006;367;397-403 Clinical recognition of meningococcal disease in children and adolescents_REF-2803.

[5] Pelton, S.I. *Meningococcal disease awareness: Clinical and epidemiological factors affecting prevention and management in adolescents*, Journal of Adolescent Health, 2009; 46(2).

[6] World Health Organization (WHO), Meningitis Factsheet, 2023. Available at: https://www.who.int/news-room/fact-sheets/detail/meningitis. Accessed November 2024.

[7] Invasive meningococcal disease – Annual Epidemiological Report for 2022: Available at: https://www.ecdc.europa.eu/en/publications-data/invasive-meningococcal-disease-annual-epidemiological-report-2022. Accessed November 2024.

[8] 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.

[9] Data on File: *List of countries where Menveo is registered and/or commercialized*_ REF-19494.

[10] 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.

[11] 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.

[12] EMA, Menveo: EPAR - Product Information – Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/menveo. Accessed November 2024.

[13] Data on File: *Menveo Doses Shipped from 2010 to end of 2022*_REF-195452.

[14] Data on file: *Menveo doses distributed in Europe from 2017 to August 31st 2024*_REF-246217.