Stock-exchange announcement
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Issued: 13 November 2026, London UK

Bexsero (4CMenB) receives positive CHMP opinion for one-dose Meningitis B booster for 10+ year olds

- Recommendation based on data showing immune memory established following vaccination in infancy can be boosted up to 19 years later[1]
- Once approved, the single-dose booster could help vaccination programmes maintain protection into adolescence, when disease incidence reaches a second peak[2]

GSK plc (LSE/NYSE: GSK) today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended updating the *Bexsero* label to include a single booster dose for individuals aged 10 years and older who were previously vaccinated at least two years earlier with *Bexsero*. The recommendation is supported by data showing that immune memory established following primary vaccination in infancy can be boosted with a single dose up to 19 years later[1].

Sanjay Gurunathan, Senior Vice President, R&D Vaccines & Infectious Diseases, GSK, said: "As the first generation of children vaccinated against MenB in infancy reaches adolescence, today's positive CHMP opinion supports maintaining protection with a single booster dose during a second period in life of increased disease risk. If adopted, adolescent boosters could help reduce the overall burden of Invasive Meningococcal Disease (IMD) in countries with established infant MenB programmes".

While Invasive Meningococcal Disease (IMD) is uncommon, it can progress rapidly and become life-threatening[3]. Disease incidence is highest in infants and young children, with a second peak in adolescents and young adults[2]. Adolescents are more likely to catch or pass on these bacteria because they often spend more time socialising, live closely with others, and may share personal items[4]. In Europe, serogroup B is the leading cause of invasive meningococcal disease in all age groups under 65 years[2].

The CHMP's positive opinion is based on data from Men-B-096, a Phase IIIb open label, multi-centre study which assessed the immune response and safety of a single booster dose of *Bexsero* in healthy individuals aged 10-20 years who previously completed their primary vaccination series with *Bexsero*. The study met its primary endpoint. The safety and reactogenicity of a single booster dose is consistent with the known safety profile of *Bexsero* in this age group.

About Men-B-096
Men-B-096 is a Phase IIIb, open label, multi-centre study assessing the immune response and safety of a single dose of *Bexsero* in healthy children aged 10-20 years. The study enrolled 312 participants across Finland, Italy, Spain and the UK, including 234 who had received *Bexsero* during infancy and 78 who had not previously received a meningococcal B vaccine. The primary endpoint was to assess the superiority of the immune response to a single booster dose in previously vaccinated participants compared with a first dose in adolescents who hadn't received a MenB vaccine in the past.

About invasive meningococcal disease (IMD)
IMD is an uncommon but serious infection caused by *Neisseria meningitidis* that can present as meningitis and/or septicaemia (blood poisoning). Although anyone can develop the disease, incidence is highest among infants and young children, with a second peak in adolescents and young adults[2]. IMD can progress rapidly and may result in death or long-term complications despite treatment.[5,6]

About Bexsero (4CMenB)
Bexsero is registered in 61 countries for the prevention of Invasive Meningococcal Disease (IMD) caused by *Neisseria meningitidis* serogroup B. In Europe, it is included in 15 national and/or regional immunisation programmes for infants, and 3 national immunisation programmes for adolescents, with additional infant vaccination

programmes funded at a regional level in some countries[7]. Around 140 million doses of *Bexsero* have been distributed globally since 2015[8].

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 www.gsk.com.

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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 2025, and GSK's Q3 Results for 2026.

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6. McMillan M, McDonough J, Angliss M, Buttery J, Saunders L, Mathew SM, Shaw D, Gordon D, Warner MS, Nelson R, Hannah R, Marshall HS. Exploring the Health-Related Quality of Life and the Lived Experience of Adolescents Following Invasive Meningococcal Disease. Healthcare (Basel). 2024 May 24;12(11):1075. doi: 10.3390/healthcare12111075. PMID: 38891151; PMCID: PMC11172222.
7. GSK Data on file, REF-343997. Bexsero is included in 15 national immunisation programmes for infants, and 3 national immunisation programmes for adolescents
8. GSK Data on file, REF-310855. 140 million doses shipped from 2015 to October 2025.