US FDA approves Menveo in a new single-vial presentation to help prevent disease caused by meningococcal bacteria serogroups A, C, Y, and W

PUBLISHED OCT 17, 2022
BY GSK

For media and investors only

Single-vial presentation option removes the need for reconstitution of Menveo before use in individuals 10 through 55 years of age.

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved a new presentation of Menveo [Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diptheria CRM197 Conjugate Vaccine] for individuals aged 10 to 55 years to help prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, and W. The Menveo one-vial presentation now comes in a ready to use single vial giving healthcare providers a more convenient option. The Menveo one-vial presentation will initially be available to US federal customers, with broader availability anticipated in mid-2023.

Invasive meningococcal disease (IMD), known as meningitis, is an uncommon but serious illness that can cause life-threatening complications or even death. IMD is caused by Neisseria meningitidis, with the majority of cases caused by serogroups (A, B, C, W, Y) in most of the world. Among those who contract meningitis, one in ten will die, despite treatment, sometimes in as little as 24 hours.

Roger Connor, President, Vaccines and Global Health, GSK, said:

> Outbreaks of this dangerous disease continue to occur, impacting families, health systems and society. This FDA approval of Menveo one-vial presentation offers greater convenience to healthcare providers to help prevent this

disease in at-risk populations in the United States.

The original two-vial presentation of Menveo requiring reconstitution, was approved by the FDA in 2010 and remains available for use in individuals from two months to 55 years of age.

The Menveo vaccine (supplied in a two-vial presentation) for meningococcal groups A, C, Y, and W has been approved in over 60 countries, with more than 72 million doses distributed worldwide since 2010. It offers extensive evidence of immunogenicity and a well-characterised safety profile. Menveo does not prevent Neisseria meningitidis serogroup B infections.

The US Prescribing Information.

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 the labeled safety information.

- Do not administer Menveo to individuals with a severe allergic reaction (e.g., anaphylaxis) to a previous dose of Menveo, to any component of this vaccine, or to any other diphtheria toxoid-containing vaccine.

- Appropriate medical treatment must be available should an acute allergic reaction, including an anaphylactic reaction, occur following administration of Menveo.

- Syncope (fainting) has occurred in association with administration of Menveo. Procedures should be in place to avoid injury from fainting.

- Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to Menveo.

- Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by meningitidis, including invasive disease caused by serogroups A, C, Y, and W, even if they develop antibodies following vaccination with Menveo.

- Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of another US-licensed meningococcal quadrivalent polysaccharide conjugate vaccine. The decision to administer Menveo to individuals with a history of GBS should take into account the expected benefits and potential risks.

- Apnea following intramuscular vaccination has been observed in some infants born prematurely. A decision about when to administer Menveo to an infant born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination.

- Common solicited adverse reactions among children initiating vaccination: at 2 months of age and receiving the 4-dose series were 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 and receiving the 2-dose series were tenderness and erythema at injection site, irritability, sleepiness, persistent crying, change in eating habits, and diarrhea; at 2 through 10 years of age who received Menveo were injection site pain, erythema, irritability, induration, sleepiness, malaise, and headache. Common solicited adverse reactions among adolescents and adults aged 11 through 55 years who received a single dose of Menveo were pain at the injection site, headache, myalgia, malaise, and nausea. Across all age groups, some events were severe. Similar rates of solicited adverse reactions among adolescents and adults were observed following a single booster dose.

- In two clinical studies, there were no notable differences in frequency and severity of solicited adverse reactions in individuals who received Menveo one-vial presentation compared to individuals who received the 2-vial presentation.

- Vaccination with Menveo may not result in protection in all vaccine recipients.

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/company

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 in the Company's Annual Report on Form 20-F for 2021, GSK's Q2 Results for 2022 and any impacts of the COVID-19 pandemic.

Centers for Disease Control and Prevention. Vaccine Information Statements. Available at: Meningococcal Vaccine Information Statement | CDC. Accessed October 2022.

Press release distributed by Wire Association on behalf of GSK, on Oct 17, 2022. For more information subscribe and follow us.

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