Menveo®: A Vaccine Targeting Meningococcal Disease

- Menveo is the first and only quadrivalent meningococcal conjugate vaccine approved in the US for persons 2 months to 55 years of age.¹
- Menveo now offers the most comprehensive age range coverage in the US against meningococcal disease caused by serogroups A, C, Y and W-135.²

Menveo® (Meningococcal [Groups A, C, Y and W-135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine) is a quadrivalent meningococcal conjugate vaccine (MCV4) approved by the US Food and Drug Administration (FDA) for the prevention of meningococcal disease caused by four strains of the bacterium Neisseria meningitidis (N. meningitidis) in infants and toddlers from 2 months of age.¹ These N. meningitidis serogroups – A, C, Y and W-135 – are four of the five most common serogroups that cause meningococcal disease.¹,²

Menveo is approved to help protect the following groups with the following dosing schedule:

- **Infants 2 months of age**: Menveo is to be administered as a four-dose series at 2, 4, 6, and 12 months of age.¹
- **Children 7-23 months of age**: Menveo is to be administered as a two-dose series with the second dose administered in the second year of life and at least three months after the first dose.¹
- **Children 2-10 years of age**: Menveo is to be administered as a single dose. For children 2 years through 5 years of age at continued high risk of meningococcal disease, a second dose may be administered 2 months after the first dose.¹
- **Adolescents and adults 11-55 years of age**: Menveo is to be administered as a single dose.¹

Class of Vaccines

Menveo belongs to a class of vaccines known as polysaccharide protein conjugates. Some bacteria, such as those that cause meningococcal and pneumococcal disease, are coated with polysaccharides – large carbohydrates – that help cloak them from the immune system. To target these bacteria, polysaccharide protein conjugate vaccines – or conjugate vaccines – were developed by attaching the antigen of polysaccharide bacteria to a carrier protein, which helps stimulate the immune system.³

Development

Menveo is the result of 10 years of innovative science led by Novartis and its award-winning researchers. As of June 2013, Menveo is registered in more than 50 countries for active immunization to prevent invasive meningococcal disease caused by N. meningitidis serogroups A, C, Y and W-135.⁵ Studies are ongoing in infants, toddlers, adolescents and adults.⁶

The Novartis Vaccines and Diagnostics division is a leader in providing products to fight more than 20 vaccine-preventable viral and bacterial diseases.⁴
Clinical Studies

### Infants

#### Safety

| Design | The safety of Menveo in infants vaccinated at 2, 4, 6 and 12 months of age was evaluated in three randomized multicenter clinical studies conducted in the US, Australia, Canada, Taiwan and several countries of Latin America in which 8,735 infants received at least one dose of Menveo and routine infant vaccines. |
| Safety findings | The largest multinational Menveo safety study showed that in infants initiating vaccination at 2 months of age and receiving the four-dose series, common solicited adverse reactions (> 10%) were tenderness (24-41%) and erythema at injection site (11-15%), irritability (42-57%), sleepiness (29-50%), persistent crying (21-41%), change in eating habits (17-23%), vomiting (5-11%) and diarrhea (8-16%). |

#### Immunogenicity

| Design | The effectiveness of Menveo in infants was assessed in a randomized, controlled, multicenter study which measured hSBA seroresponse ≥ 1:8 one month following final dose. |
| Immunogenicity findings | In infants from 2 months of age, the pre-defined criteria for immunogenicity were met for all four serogroups A, C, Y and W-135 at one month following completion of a four dose series at 2, 4, 6 and 12 months of age. |

### Children

| N= | 2,331 (stratified by age; 2-5 years of age and 6-10 years of age) |
| Design | Randomized, multicenter, active controlled comparing the hSBA responses following one dose of Menveo (N=1170) and Menactra® (N=1161) |
| Primary Endpoint(s) | hSBA seroresponse to each serogroup 28 days after vaccination |
| Immunogenicity | In study participants 2 through 5 years of age and 6 through 10 years of age, non-inferiority of Menveo to Menactra for the proportion of people with a seroresponse was demonstrated for serogroups C, Y and W-135, but not for serogroup A |
Adolescents & Adults

| N= | 3,539 (stratified by age; 11-18 years of age and 19-55 years of age) |
| Design | Randomized, multicenter, active controlled comparing the hSBA responses following one dose of Menveo (N=2663) and Menactra (N=876) |
| Primary Endpoint(s) | hSBA seroresponse to each serogroup 28 days after vaccination |
| Immunogenicity | In study participants 19 through 55 years of age, non-inferiority of Menveo to Menactra was demonstrated for all four serogroups for the proportion of subjects with a seroresponse |

In the US, there is currently no approved vaccine, including Menveo, to help protect against meningitis serogroup B infections⁴.

For more information about Menveo, visit www.menveo.com.

Indication and Important Safety Information

Severe allergic reaction (e.g., anaphylaxis) after a previous dose of Menveo, any component of this vaccine, or any other CRM197, diphtheria toxoid or meningococcal-containing vaccine is a contraindication to administration of Menveo. Appropriate medical treatment must be available should an acute allergic reaction, including an anaphylactic reaction, occur following administration of Menveo.

Syncope, sometimes resulting in falling injury associated with seizure-like movements has been reported following vaccination with Menveo. Vaccinees should be observed for at least 15 minutes after vaccine administration to prevent and manage syncopal reactions.

Safety and effectiveness of Menveo have not been evaluated in immunocompromised persons. If Menveo is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the expected immune response may not be obtained.

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

Apnea following intramuscular vaccination has been observed in some infants born prematurely. The decision about when to
administer an intramuscular vaccine, including 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.

In clinical trials, common solicited adverse reactions with Menveo among children initiating vaccination at 2 months of age and receiving the four-dose series were tenderness and erythema at injection site, irritability, sleepiness, persistent crying, change in eating habits, vomiting and diarrhea. Common solicited adverse reactions among children initiating vaccination at 7 months through 23 months of age and receiving the two-dose series were tenderness and erythema at injection site, irritability, sleepiness, persistent crying, change in eating habits and diarrhea. Common solicited adverse reactions among children 2 years through 10 years of age were injection site pain, erythema, irritability, induration, sleepiness, malaise, and headache. Common solicited adverse reactions among adolescents and adults were pain at the injection site, headache, myalgia, malaise and nausea. Some events were severe. Safety has not been established in pregnant women. Vaccination with Menveo may not protect all individuals.

Before administering Menveo, please see full Prescribing Information.

References