FDA expands age indication for Menveo®, first and only quadrivalent meningococcal vaccine for infants as young as 2 months of age¹

- Meningococcal disease is a leading cause of bacterial meningitis, a rapidly progressing disease that can lead to death in otherwise healthy children²,³
- The highest rates of meningococcal disease in the US occur in infants; babies younger than 7 months old are the most vulnerable⁴
- Menveo now offers the most comprehensive age range coverage in the US against meningococcal disease caused by serogroups A,C, Y and W-135¹

Cambridge, MA, August 1, 2013 – Novartis announced today that the US Food and Drug Administration (FDA) approved Menveo® (Meningococcal [Groups A, C, Y and W-135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine) to help prevent meningococcal disease caused by four strains of the bacterium Neisseria meningitidis (N. meningitidis) in infants and toddlers from 2 months of age¹. With this expanded indication, pediatricians in the US can now offer a single vaccine to help protect infants, children and adolescents against four of the five most common serogroups that cause meningococcal disease¹,⁵.

“Each year, more children in the US die or are left with permanent disability from meningococcal disease than from two other diseases combined that we routinely vaccinate infants against - rotavirus and varicella,” said Dr. Steve Black, Center for Global Health, University of Cincinnati Children's Hospital. “With the expanded indication for this MCV4 vaccine, we now have the opportunity to help protect our infants against four strains of meningococcal disease earlier, when they are most vulnerable.”

Infants younger than 7 months old are the most vulnerable age group to meningococcal disease in the US. In their first year of life, infants are about seven times more likely to contract the disease than 14 to 24 year olds⁴.

“Despite recommendations for routine immunization of adolescents, college students living in dormitories and certain infants in the US, meningococcal disease continues to kill and maim,” said Andrin Oswald, Head of Novartis Vaccines and Diagnostics. “With this approval for the expanded use of Menveo, we hope that health authorities will deploy this vaccine to further reduce the burden of this devastating disease in the US.”

This FDA approval was based on data from three randomized multicenter studies involving more than 8,700 infants, conducted in Australia, Canada, Latin America, Taiwan and the US. The studies demonstrated that Menveo generated a robust protective immune response and a demonstrated safety profile when co-administered with routine pediatric vaccines¹.

In the US, there is currently no approved vaccine, including Menveo, to help protect against meningitis serogroup B infections¹.
About Menveo
Menveo is a quadrivalent conjugate vaccine for use to help protect against invasive disease caused by four groups of the bacterium Neisseria meningitidis (A, C, Y and W-135). As of July 2013, Menveo is registered in more than 50 countries for active immunization to help prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W-135 and Y. Studies are ongoing in infants, toddlers, adolescents and adults.

Menveo has been available for use in adolescents and adults (11 to 55 years of age) since February 2010 and in children (2 to 10 years of age) since January 2011.

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

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 US-licensed meningococcal quadrivalent polysaccharide conjugate vaccine. The decision to administer Menveo to subjects with a known history of GBS 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 pain at the 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.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by terminology such as “can,” “opportunity,” “hope,” “will,” “potential,” “may,” or similar
expressions, or by express or implied discussions regarding potential new indications or labeling for Menveo or regarding potential future revenues from Menveo. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Menveo to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Menveo will be approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Menveo will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Menveo could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; the impact that the foregoing factors could have on the values attributed to the Novartis Group’s assets and liabilities as recorded in the Group’s consolidated balance sheet, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis
Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 131,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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References

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