

MEDIA RELEASE • MEDIA RELEASE • MEDIA RELEASE**Novartis vaccine Menveo[®] now supported by three years of immune persistence and safety data^{1a}**

- *New data also demonstrate that Menveo can boost the immune response to serogroups ACWY in adolescents previously vaccinated with a conjugate meningococcal vaccine^{1b}*
- *Meningococcal disease can lead to death within 24 to 48 hours of the first symptoms^{2a} therefore maintaining high levels of circulating antibodies is critical for protection*
- *The CDC recommends routine immunization with a quadrivalent meningococcal conjugate vaccine for all adolescents at 11 or 12 years of age, and a booster dose at age 16³*

Cambridge, MA May 12, 2011 – Novartis announces today that new data from an ongoing, Phase III extension study showed that, although immune responses wane over time, the majority of adolescents vaccinated with Menveo[®] [Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM₁₉₇ Conjugate Vaccine] had a protective immune response after three years against the most common vaccine-preventable causes of meningococcal disease in the US^{1a}.

Findings also showed that Menveo can be used as an adolescent booster dose for quadrivalent meningococcal conjugate vaccines, regardless of which vaccine was used for the initial immunization^{1b}.

“Adolescents are at increased risk for invasive meningococcal disease, which strikes suddenly, progresses rapidly and can be fatal, even with proper antibiotic treatment^{2a, 4, 5},” said Gary S. Marshall, MD, Professor of Pediatrics at the University of Louisville School of Medicine. “These data show that three years after vaccination with Menveo a high proportion of adolescents continue to have protective antibody levels^{1a}. The study also demonstrates that booster responses occur after revaccination with Menveo, something that is particularly important given the recent CDC recommendation for routine booster doses^{1b, 3}.”

The three year data are consistent with five year persistence data from a separate Menveo Phase IIb study also recently presented at the 2011 joint meeting of the Pediatric Academic Societies (PAS) and Asian Society for Pediatric Research (ASPR) in Denver, Colorado^{1a, 6}.

Study Results

The three year study measured the persistence of antibody response over time in vaccinated adolescents. The data showed that, 36 months after being vaccinated with one dose of the meningococcal ACWY-CRM conjugate vaccine, Menveo, a majority of adolescents (11 to 18 years old), had a protective immune response (hSBA titer \geq 1:8) against meningococcal

serogroups C, W-135 and Y (64%, 82% and 65%, respectively). The percentages for adolescents receiving the other US-licensed ACWY meningococcal conjugate vaccine were 62%, 71% and 53%, respectively; while in the age-matched unvaccinated control group the percentages were 43%, 58% and 40%, respectively^{1c}. Nearly all vaccine-preventable meningococcal disease in the US is caused by serogroups C, Y and W-135⁷. For serogroup A, the percentage of participants who had a protective immune response was 28% when vaccinated with Menveo, 21% when vaccinated with the comparator vaccine and 7% in the unvaccinated control group had protective titers^{1c}. The study was not designed to assess the difference of antibody response between Menveo and the comparator vaccine and the clinical significance of the differences observed is unknown.

Another objective of this ongoing Phase III extension study was the evaluation of immune response when Menveo was given as a booster dose to adolescents three years after receiving either Menveo or the other US-licensed ACWY meningococcal conjugate vaccine. One month after the booster dose, 100% of recipients initially vaccinated with Menveo achieved a protective immune response against all four serogroups. When the first dose was the other US-licensed ACWY meningococcal conjugate vaccine, and the booster dose was Menveo, the results were: A 100%; C 100%; W-135 99%; and Y 99%^{1b}. Local and systemic reactions were independent of which vaccine was used for priming^{1d}.

In October 2010, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) announced recommendations for routine immunization with a quadrivalent meningococcal conjugate vaccine for all adolescents at 11 or 12 years of age, with a new recommendation for a booster dose at age 16. For adolescents who received the vaccine at age 13 through 15 years under previous guidelines, a one-time booster dose should be administered, preferably at age 16 through 18 years. Those who received the vaccine at or after age 16 do not need a booster dose³.

Phase III Extension Study Design

The Phase III extension study analyses were from two subsets of adolescents who received either Menveo or the other US-licensed ACWY meningococcal conjugate vaccine and were then enrolled in a follow-up observational study. The 36-month immunogenicity study included 275 subjects initially randomized to receive Menveo and 179 subjects initially randomized to receive the other vaccine, along with 97 unvaccinated age-matched controls. Immune response was measured using the human serum bactericidal antibody (hSBA) assay^{1e}.

The booster analysis in the same trial included 72 participants who received Menveo as their initial vaccination and 79 who received the comparator vaccine. Immune response was measured using the hSBA assay and was assessed one month post booster dose^{1e}. The most common local reactogenicity events included injection site pain, skin redness (erythema) and hardening of the skin (induration). The most common systemic events included headache, muscle pain (myalgia), malaise, nausea, joint pain (arthralgia), chills, rash and fever^{1d}.

The data were presented during a poster session at the 2011 joint meeting of the Pediatric Academic Societies (PAS) and Asian Society for Pediatric Research (ASPR) in Denver, Colorado.

Meningococcal Disease Causes and Incidence

Meningococcal disease is a leading cause of bacterial meningitis – an infection of the membrane around the brain and spine – and sepsis – a bloodstream infection^{2b, 8a}. It is a sudden, contagious and aggressive illness that can lead to death within 24 to 48 hours of the first symptoms^{2a, 5}. As many as one in seven patients who contract meningococcal disease

die from it^{9a}. Approximately one in five meningococcal disease survivors suffer serious, permanent and devastating consequences, including limb loss, seizures, paralysis, hearing loss and learning disabilities^{8b}.

Five serogroups – A, B, C, Y and W-135 – cause the majority of meningococcal disease cases worldwide, and distribution of serogroups varies widely from geographic region to region and changes over time^{10a, 10b}. Globally, there are more than 500,000 cases of meningococcal disease in all age groups each year, leading to more than 50,000 deaths¹¹.

In the US, incidence of meningococcal disease is variable. Between 1975 and 2006, there were approximately 1,200 to 3,500 cases of meningococcal disease each year^{8c}. Currently in the US, meningococcal disease caused by serogroups C, Y and W-135 account for nearly 70 percent of all cases⁷. The remainder is caused by serogroup B, for which there is currently no licensed broad coverage vaccine^{9b}.

In the US, routine immunization with a quadrivalent meningococcal conjugate vaccine is recommended for all adolescents 11 to 18 years of age, college freshmen living in dormitories and people in other high risk groups who are 19 to 55 years of age. Vaccination is also recommended for children 2 to 10 years of age who are at increased risk for meningococcal disease^{9c}.

About Menveo

As of April 2011, Menveo is registered in more than 40 countries for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y. Menveo has been administered to more than 18,500 participants in clinical trials across all age groups worldwide, and studies are ongoing in infants, toddlers, adolescents and adults¹². Menveo received FDA approval in February 2010 for use in adolescents and adults (11 to 55 years of age) and approval for use in children 2 to 10 years of age in January 2011. In April, Novartis re-submitted a sBLA seeking an indication for use of Menveo in infants and toddlers 2 to 23 months of age.

In the European Union, Menveo is indicated for use in persons 11 years and above. Novartis Vaccines plans to submit additional data to the European Medicines Agency to support the use of Menveo in infants and children 0 to 10 years of age in the first half of 2011. The label extension for use in children 2 to 10 years of age has been submitted in Canada.

Important Safety Information

Menveo is contraindicated in individuals who have experienced a severe allergic reaction after a previous dose of Menveo, any component of this vaccine, or any other CRM₁₉₇-, diphtheria toxoid-, or meningococcal-containing vaccine. Appropriate medical treatment must be available should an acute allergic reaction, including an anaphylactic reaction, occur following administration of Menveo.

Vaccinees may develop syncope, sometimes resulting in falling with injury associated with seizure-like movements. Observation for 15 minutes after vaccination is recommended. Patients who are immunocompromised or receiving immunosuppressive therapy may have an inadequate response to vaccination.

Following vaccination with another US-licensed meningococcal quadrivalent polysaccharide conjugate vaccine, an evaluation of postmarketing adverse events suggested a potential for an increased risk of Guillain-Barré syndrome (GBS). Data are not available to evaluate the potential risk of GBS following administration of Menveo.

In clinical trials, the most frequently occurring adverse events in subjects 11 to 55 who received Menveo were pain at the injection site, headache, myalgia, malaise, and nausea. The most frequently occurring adverse events in subjects 2-10 years of age who received Menveo were pain at the injection site, erythema, irritability, induration, sleepiness, malaise, and headache. 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,” “seeking,” “plans,” 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 submitted or approved for any additional indications or labeling in any market. 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; 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 Vaccines and Diagnostics is a division of Novartis, focused on the development of preventive treatments. The division has two businesses: Novartis Vaccines and Novartis Diagnostics. Novartis Vaccines is the world’s fifth-largest vaccines manufacturer and second-largest supplier of flu vaccines in the US. The division’s products also include meningococcal, pediatric and travel vaccines. Novartis Diagnostics, the blood testing business, is dedicated to preventing the spread of infectious diseases through the development of novel blood-screening tools that protect the world’s blood supply.

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only company with leading positions in these areas. In 2010, the Group’s continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>.

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12. Novartis Data on File.

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Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff

Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Elizabeth Power

Novartis Division Communications
+1 617 871 7985 (direct)
+1 617 583 3015 (mobile)
elizabeth.power@novartis.com

e-mail: media.relations@novartis.com

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For questions about the site or required registration, please contact:

journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone: +41 61 324 7944

Susanne Schaffert +41 61 324 3769
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America:

Richard Jarvis +1 212 830 2433
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456

e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com