

## **New data show Menveo™ to be the first quadrivalent meningococcal vaccine to provide immunogenicity in infants**

- *Data in JAMA show Menveo may provide infants protection against four of the most common meningococcal serogroups – A, C, W-135 and Y*
- *Menveo stimulates broad immune response against meningococcal disease in infants from two months old*

**Basel, January 9, 2008** — Menveo™ (MenACWY-CRM), a vaccine in development by Novartis, may protect infants using a schedule beginning at two months of age against four of the most common causes of meningococcal disease. Menveo is the only meningococcal vaccine shown to generate protection against a broad range of serogroups in infants, potentially filling a large unmet medical need.

New data, published in the *Journal of the American Medical Association*, show that Menveo was well-tolerated and generated high levels of immunogenicity in infants against meningococcal serogroups A, C, W-135 and Y with a standard infant vaccination dosing schedule.

Infants have the highest rate of meningococcal disease, a potentially deadly bacterial infection. However, no currently available quadrivalent vaccine including Menomune®\* and Menactra®† has demonstrated a strong and lasting immune response for this age group.

“These important data show that this new MenACWY vaccine has the potential to protect infants as part of the routine infant vaccine schedule, expanding the potential serogroup coverage of currently available vaccines,” said study investigator Andrew Pollard, FRCPCH, PhD, Reader in Paediatric Infection & Immunity, University of Oxford and Honorary Consultant Paediatrician at Children’s Hospital in Oxford, England.

“Infants have the highest rate of meningococcal disease, and to date no quadrivalent vaccine has been immunogenic in this high risk age group,” said Steve Black, MD, Adjunct Professor of Pediatric Infectious Disease at Stanford University. “These new data are encouraging and offer promise that we will soon have a vaccine to protect all children against a broad range of serogroups that cause meningococcal disease.”

These new results build on numerous other clinical trial findings, which support that Menveo generates a strong immune response across all age groups. Novartis plans regulatory submissions for Menveo in the European Union and the United States in 2008.

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\* Menomune is a registered trademark of Sanofi Pasteur

† Menactra is a registered trademark of Sanofi Pasteur

“Novartis is making great progress toward our goal of protecting all age groups from all causes of meningococcal disease,” said Joerg Reinhardt, CEO of Novartis Vaccines and Diagnostics.

A rare but potentially vaccine-preventable disease, invasive meningococcal disease is an acute, contagious and potentially fatal disease that causes sepsis and meningitis, an infection of membranes around the brain and spinal cord. Each year, approximately 500,000 cases occur around the world, causing about 50,000 deaths. Meningitis symptoms – which can include sudden onset of fever, rash, headache and stiff neck – can progress rapidly. Even with early and appropriate treatment, patients can die, typically within 24-48 hours. Up to 20% of those who survive infection are left with life-long disability, such as deafness, neurological damage or limb loss.

### **About the trial**

The Phase II randomized, open-label trial included 421 infants from the UK and Canada and evaluated multiple schedules including two 3-dose primary schedules, at either 2, 3 and 4 months and 2, 4 and 6 months. Some participants received either an additional dose of MenACWY-CRM or a plain meningococcal polysaccharide at 12 months. One month after the last primary immunization, the percentage of participants with hSBA titers greater than or equal to 1:4 in the 2, 3, 4-month group was 93% or above for all four serogroups. Immunization at 2, 4 and 6 months resulted in a similarly high percentage of participants achieving immune response for serogroups C, W-135 and Y, and 81% for serogroup A. The dose at 12 months generated a strong immune response across all four serogroups, was shown to increase levels of immunity, and is likely to provide sustained protection. The hSBA titer is the human serum bactericidal antibody assay, which measures the body’s protective immune response to the meningococcus.

### **About Menveo**

Menveo is currently in multiple Phase III clinical trials involving infants, young children, adolescents and adults. It is based on the same technical expertise Novartis used to produce Menjugate®, a meningococcal serogroup C conjugate vaccine approved outside the United States since 2000 for use in individuals from two months old through adulthood.

The polysaccharide conjugation technique used to produce MenACWY-CRM improves immunization responses compared to older polysaccharide vaccines, which are poorly immunogenic in infants. Currently the only conjugate vaccines approved and available for use in infants protect only against serogroup C; these serogroup C vaccines are not approved in the United States. Menveo will therefore provide the opportunity to protect infants against a broad range of serogroups that cause meningococcal disease.

Novartis is a global leader in providing effective meningococcal vaccines, having distributed more than 26 million doses of Menjugate around the world and producing MenZB, a vaccine against a strain of meningococcus B specific to a recent outbreak in New Zealand. Novartis is also developing a recombinant vaccine to provide broad coverage against multiple strains of serogroup B, which no vaccine currently available can achieve.

### **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 Chiron. 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. Chiron, the blood testing and molecular diagnostics 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 AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 associates and operates in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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