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## **New data for Menveo™ vaccine show excellent immune response and broad protection for infants against meningococcal meningitis**

- *Menveo™ (MenACWY-CRM) the first quadrivalent conjugated meningitis vaccine to demonstrate an excellent immune response in infants<sup>1</sup>*
- *Infants considered the highest at-risk group in need of protection against four common meningococcal meningitis serogroups – A, C, W-135 and Y*
- *Menveo currently on track for regulatory submissions in 2008; conjugated technology offers improved immune response over older bacterial polysaccharide vaccines*

Basel, November 15, 2007 — New clinical data for the Novartis development vaccine Menveo™<sup>2</sup> (MenACWY-CRM) show an excellent and broad immune response in infants as young as six months of age against four common serogroups (or types) of meningococcal meningitis, a potentially fatal bacterial disease involving inflammation of membranes around the brain and spinal cord.

Menveo is currently the only vaccine to generate protective immune responses in infants, expanding beyond the coverage of currently available vaccines for teenagers and adults. This response was seen in all four of the common serogroups – A, C, W-135 and Y – associated with meningococcal meningitis, which is caused by the bacteria *Neisseria meningitidis*.

The infant clinical trial data for this conjugated meningococcal vaccine, which utilizes technology that offers improved immunization responses compared to older bacterial polysaccharide vaccines, were presented for the first time today at the 5<sup>th</sup> World Congress of The World Society for Pediatric Infectious Diseases (WSPID) in Bangkok.

Using a flexible administration schedule, results from the Phase II study of 175 infants who received either two doses of Menveo at ages six and 12 months or one dose of Menveo at age 12 months showed a robust immune response against serogroups A, C, W-135, and Y after one month<sup>1</sup>.

The data reinforce earlier findings showing that Menveo – which is currently on track for regulatory submissions in 2008 – was well-tolerated and immunogenic in the first year of life and has the potential to protect against the A, C, W-135 and Y serogroups from early infancy<sup>3</sup>.

“These data are encouraging given the unmet need for an effective meningococcal meningitis vaccine with broad serogroup coverage that can be given to infants,” said Scott Halperin, MD, the lead study investigator and Director of the Canadian Center for Vaccinology as well as Professor of Pediatrics and Microbiology and Immunology at Dalhousie University in Halifax, Canada.

Meningococcal meningitis primarily affects young children, with the highest attack rate seen in infants during the first 3 to 12 months of life<sup>4</sup>.

However, currently available polysaccharide vaccines covering these serogroups (called “quadrivalent vaccines”) are only approved in certain countries for use in children age two and older due mainly to poor efficacy, while a conjugated vaccine approved for use in infants is only available against the C serogroup.

Approximately 500,000 cases of meningococcal meningitis are estimated to occur each year around the world, with 50,000 deaths blamed on the disease annually<sup>4</sup>. Up to 20% of those who survive are left with permanent disability such as deafness, neurological damage or limb loss<sup>5</sup>.

“Menveo has shown in clinical trials that it is well-tolerated and generates high immune responses across all age groups, including infants,” said Joerg Reinhardt, CEO of Novartis Vaccines and Diagnostics. “Novartis is rapidly developing this vaccine in a broad range of ages as an effective new option against meningitis and expects to make regulatory submissions in 2008.”

Menveo is currently in multiple Phase III clinical trials involving infants, young children, adolescents and adults. It is based on the same technical expertise used to produce Menjugate<sup>®</sup>, a meningococcal serogroup C conjugate vaccine of Novartis approved outside the US since 2000 for use in individuals from two months old through adulthood. More than 25 million doses of Menjugate have been distributed around the world.

In addition to Menveo, Novartis is developing a recombinant vaccine aiming to provide coverage against the B serogroup, for which no vaccine has been achieved.

### **Menveo has high protective antibody levels with two different dosing schedules<sup>1</sup>**

The Phase II multi-center trial randomized 175 infants to receive either two doses of Menveo at both six and 12 months of age, one dose of Menveo at age 12 months or a currently approved meningococcal meningitis serogroup C vaccine also at age 12 months and then followed by Menveo at age 18 months.

One month after vaccination, infants receiving Menveo achieved protective antibody levels as measured by hSBA titer  $\geq 1:4$  for all four meningococcal serogroups. hSBA is the human serum bactericidal antibody assay, which measures the body’s immune response to antigens. After two doses of Menveo, the percentage of subjects achieving hSBA titer  $\geq 1:4$  was 100% for the serogroups C, W-135 and Y35 and 86% for serogroup A<sup>1</sup>. After a single dose of Menveo at age 12 months, the percentages were  $\geq 93\%$  for serogroups C and W-135 as well as  $\geq 75\%$  for serogroups A and Y. Of the subjects who received the Menveo booster at age 18 months following a single dose at age 12 months, 100% achieved hSBA titers  $\geq 1:4$  for serogroup C, 62% for A, 84% for W-135 and 81% for Y. Menveo was well-tolerated in this population<sup>1</sup>.

Two doses of Menveo led to markedly greater amounts of antibody levels, while one dose at age 12 months led to comparable titers for serogroup C compared to the existing meningitis C vaccine<sup>1</sup>.

### **Disclaimer**

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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 operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

### **References**

1. Halperin SA et al. Safety and immunogenicity of Novartis Vaccines MenACWY Conjugate Vaccine After One or Two Doses Administered to Infants and Young Children. Poster Presentation at World Society for Pediatric Infectious Diseases Annual Meeting (WSPID), November 2007.
2. Brand name awaiting regulatory approval.
3. Perrett, KP et al. Immunogenicity of a Tetravalent Meningococcal Glycoconjugate Vaccine in Infants. Presented at Infectious Diseases Society of America (IDSA) annual meeting, 2006.
4. WHO Weekly Epidemiological Record. Meningococcal Vaccines: Polysaccharide and Polysaccharide Conjugate Vaccines. 40(77); 329-340, 2002.
5. Centers for Disease Control and Prevention. Factsheet: Meningococcal Diseases and Meningococcal Vaccines. April 25, 2006. Available at: <http://www.cdc.gov/vaccines/vpd-vac/mening/vac-mening-fs.htm>

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