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New Phase II data show Novartis investigational Meningitis B vaccine may also protect infants six months and older

- *Novel vaccine produced protective immune response against broad range of representative meningococcal B strains in more than 95% of infants tested¹*
- *Novartis MenB vaccine could fill major unmet need for broadly protective vaccine for children and infants two months and older*
- *Meningococcal B strains cause 72% of meningococcal disease in Europe and 28% in the US; infants and toddlers are the age group most at risk^{2, 3}*

Basel, September 10, 2008 — New data show the investigational Novartis Meningitis B vaccine may be the first to also protect infants six months and older against multiple strains of potentially deadly meningococcal B bacteria. This second successful study of the vaccine in infants supports its potential to provide broad serogroup B strain coverage for both younger and older babies.

Nearly all infants (more than 95 percent) six to 12 months of age enrolled in the study generated a protective immune response as early as one month post-second dose against strains representing multiple antigens included in the vaccine¹.

“These are encouraging new findings that indicate the Novartis MenB vaccine may also offer infants six months and older robust protection against multiple strains of meningococcal B bacteria,” said Matthew Snape, MD, MBBS, FRCPCH, Consultant in Vaccinology, Oxford Vaccine Group, University of Oxford; Honorary Consultant Paediatrician, John Radcliffe Hospital, Oxford. “Providing broad protection against meningococcal B disease is a global health priority.”

The meningococcal B strains are a leading cause of bacterial meningitis throughout the world, particularly among infants, accounting for 72 percent of meningococcal disease in Europe in 2006. Meningococcal B infection can be a devastating disease that strikes suddenly and can kill children quickly². There is currently no broad coverage meningococcal B vaccine licensed in the European Union, United States and most other parts of the world.

The data will be shared as an oral presentation at the 16th International Pathogenic Neisseria Conference 2008 (IPNC) annual meeting in Rotterdam, The Netherlands, on 12 September and build upon a recently presented successful study in infants who received the vaccine series starting at two months of age.

Novartis MenB vaccine is the first vaccine based on recombinant proteins to demonstrate a protective immune response in infants, adults, and now older infants and toddlers. It

contains multiple bacterial surface proteins – or antigens – that are believed to be found in most meningococcal B strains responsible for the disease globally.

“The Novartis MenB vaccine could fill a tremendous global need for a broad coverage vaccine to protect infants and other age groups against meningococcal B strains,” said Joerg Reinhardt, CEO of Novartis Vaccines and Diagnostics. “With the broadest development portfolio of meningococcal vaccines in the industry, Novartis is dedicated to preventing infection from the five major causes of this deadly disease in infants, children and adults around the world.”

According to the new study results, 100 percent of the infants who received a series of three immunizations with Novartis MenB vaccine starting at six, seven, or eight months of age produced a protective immune response against two of the vaccine antigens, and 96 percent generated a protective immune response against a third antigen, as evaluated by a biomarker of clinical protection¹. Similar levels of immune response were observed one month after the second dose¹.

Novartis scientists pioneered an innovative approach called “reverse vaccinology” to develop the Novartis MenB vaccine. By first decoding the entire genetic makeup of a pathogenic meningococcal serogroup B strain, Novartis discovered 580 novel proteins. Reproduced through genetic engineering for further investigation, the vaccine contains the antigens that showed the greatest ability to stimulate the immune system to kill bacteria from a panel of strains of meningococcal serogroup B representative of global and temporal diversity.

Novartis MenB vaccine is the first potentially broad coverage meningitis B vaccine to reach phase III clinical testing, which began in the first quarter of 2008.

Novartis investigational MenB vaccine study details¹

The Novartis MenB vaccine was administered to 30 healthy children six to eight months of age, while another 30 received a version of the vaccine without the outer membrane vesicle (OMV) antigen. Immunizations were administered at enrollment, two months later and at 12 months of age. The vaccine’s protective immune response was assessed by the percentage of subjects achieving hSBA titers $\geq 1:4$ using strains representing three major vaccine antigens. One month after the third dose, the percentages of subjects achieving a protective immune response were 100 percent, 100 percent and 96 percent. One month after the second dose, the percentages were 100 percent, 100 percent and 95 percent. The hSBA assay measures the body’s protective immune response based on the ability of antibodies to kill the bacteria; an hSBA titer $>1:4$ is the threshold level accepted as providing protection against the bacteria. The vaccine was well tolerated.

Novartis is a global leader in meningitis vaccines

Novartis is a global leader in developing and providing vaccines to protect against deadly meningococcal disease. In addition to Novartis MenB vaccine, the company is developing Menveo[®] (MenACWY-CRM), a late-stage investigational vaccine for the four other common meningococcal serogroups, A, C, W-135 and Y. Novartis is currently the only company with vaccines against all five key disease-causing meningococcal serogroups in international Phase III trials.

Novartis pioneered the development of meningococcal conjugate vaccines with Menjugate[®], a meningococcal serogroup C conjugate vaccine approved outside the US since 2000 for use in individuals from two months of age through adulthood. More than 26 million doses of Menjugate have been distributed. Three million doses of MeNZB[™], an OMV vaccine against a strain of meningococcus B specific to New Zealand, have been administered to help in successfully curbing a recent outbreak there.

About meningococcal disease, a leading cause of bacterial meningitis

Meningococcal disease, a contagious and potentially deadly infection caused by the bacterium *Neisseria meningitidis* (*N. meningitidis*), may occur suddenly in previously healthy individuals. It can manifest as bacterial meningitis – an infection of the membranes around the brain and spinal cord – or sepsis, a bloodstream infection. Each year, approximately 500,000 cases of meningococcal disease occur around the world, causing about 50,000 deaths⁴. The meningococcal B strain causes the majority of meningococcal infections in developed nations including Europe, Canada, Australia and the US. In these countries, serogroup B is responsible for 28 to 80 percent of meningococcal cases^{2, 5, 6, 7}. Worldwide incidence of serogroup B disease is estimated to be 20,000 to 80,000 cases per year⁸.

The symptoms – which can include sudden onset of fever, rash, headache, and stiff neck – can progress rapidly. There are effective treatments; however, the disease can be difficult to diagnose, can progress very quickly and is associated with high fatality even with appropriate treatment. Deaths can occur within 24 hours of the onset of symptoms^{9, 10}. Up to 10 percent of cases are fatal and up to 20 percent of survivors are left with permanent disability such as deafness, neurological damage or limb loss¹¹.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “may”, “could”, “potential”, “encouraging”, “can”, “believed”, “could”, “dedicated”, “potentially”, “developing”, or similar expressions, or by express or implied discussions regarding potential future marketing approvals for Novartis MenB vaccine or regarding potential future revenues from Novartis MenB vaccine. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Novartis MenB vaccine to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Novartis MenB vaccine will be approved for sale in any market. Nor can there be any guarantee that Novartis MenB vaccine will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Novartis MenB vaccine could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; 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 AG 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group’s continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group.

Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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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

Beth Birke

Novartis Vaccines and Diagnostics

+1 (617) 871 4281 (direct)

+1 (617) 803 4359 (mobile)

beth.birke@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone: +41 61 324 7944

Ruth Metzler-Arnold +41 61 324 9980

Pierre-Michel Bringer +41 61 324 1065

John Gilardi +41 61 324 3018

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