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FORM 6-K

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- Investor Relations Release -

Novartis Phase III study shows meningococcal B vaccine candidate could be first to provide broad coverage against deadly disease

- *Pivotal data show that the large majority of infants vaccinated with Novartis investigational 4CMenB achieved robust immune response against all vaccine antigens(1)*

- *Tolerability profile supports potential use of vaccine to protect infants against a serious and often deadly disease around the globe(2)*

- *4CMenB holds promise as single multi-component vaccine that is broadly protective against a large variety of MenB strains worldwide*

Basel, September 12, 2010 New Phase III data presented by Novartis Vaccines indicate that the investigational Multicomponent Meningococcal Serogroup B Vaccine (4CMenB) has the potential to be the first broad-coverage vaccine against the dynamic and deadly meningococcal B (MenB) disease. The data were presented at the International Pathogenic Neisseria Conference (IPNC) in Banff, Canada.

This trial involving more than 3,600 infants has met its primary end points. Results show that the large majority of those vaccinated with 4CMenB at the same time as other routine vaccines achieved a robust immune response against all vaccine MenB antigens(1). Additionally, results show that 4CMenB had an acceptable tolerability profile when co-administered with other routine infant vaccines(2), which supports potential use of the vaccine in the first year of life, when the medical need is greatest(3).

These new phase III data are part of a comprehensive clinical program led by Novartis to show that 4CMenB can be used across all age groups and can be either co-administered with other routine vaccines or as part of a flexible vaccination schedule. Additional Phase III trial results from ongoing studies are expected this autumn. The comprehensive data of more than 7,500 subjects is expected to be the basis for the planned filing in the EU by year end.

MenB is a sudden, aggressive illness that can lead to death within 24-48 hours of the first symptoms(4), (5). The disease poses a significant burden to people around the world(6), especially infants, who are at highest risk for infection(3). MenB causes up to 80 percent of meningococcal disease cases in Europe(7), up to 55 percent of cases in Canada(8) and 30 percent of cases in the US(7). MenB strains circulate worldwide, can mutate and may result in long-term regional outbreaks(9).

The challenge with MenB is that there are thousands of circulating strains and developing a broadly protective vaccine has, until now, been difficult(9), said Andrin Oswald, Head of Novartis Vaccines and Diagnostics Division. These critical data highlight the promise of our innovative

candidate 4CMenB vaccine in addressing the unmet public health need of MenB, the most common cause of bacterial meningitis for which there is no readily available global vaccine(6).

The Novartis 4CMenB vaccine was developed using a pioneering approach known as reverse vaccinology. In contrast to conventional methods of producing vaccines, reverse vaccinology decodes the genetic makeup of MenB and finds the specific components that most typically cause infection(10). 4CMenB targets multiple components and is designed to provide an optimal immune response against the majority of MenB strains, while at the same time addressing the constantly changing nature of the bacteria.

Meningitis B can be devastating for affected families and is a major concern for pediatricians who care for children with this serious illness. The disease can strike healthy children without warning and, in some countries, is the leading infectious cause of death in early life(11), (12), said Andrew Pollard FRCPCH PhD, Professor of Paediatric Infection and Immunity at the University of Oxford. Many cases of meningitis are prevented today by the vaccines we give to our children, but the more complex meningitis B remains as a major threat to public health(6). The encouraging data presented on 4CMenB indicate the potential for additional protection to be provided by this new vaccine.

4CMenB Clinical Trial Results Presented at IPNC

Results from the clinical Phase III trial show that a majority of infants vaccinated with 4CMenB concomitantly with other routine vaccines achieved a robust immune response against the three vaccine MenB antigens. The vaccine was administered at 2, 4, and 6 months of age(1), (2). One month after the third 4CMenB dose, the percentage of subjects achieving serum bactericidal antibodies using human complement (hSBA) $\geq$1:5 against three MenB strains (5/99, NZ98/254 and H44/76) were 100 percent, 84 percent and 100 percent, respectively(1). All three lots of investigational 4CMenB showed highly consistent immune responses(1). In addition, responses to routine infant vaccine antigens when co-administered with 4CMenB were similar with the exception of a slightly diminished polio 2 response when compared to routine vaccine administration alone(1).

4CMenB also had an acceptable tolerability profile when co-administered with other routine infant vaccines(2). Typical vaccine associated events solicited for 7 days after each vaccination showed a similar incidence (83 percent after routine vaccine alone compared to 87 percent following routine vaccine co-administered with 4CMenB)(2). The events were similar in nature and quality (mostly injection site reactions and systemic reactions such as sleepiness, changed eating habits, irritability, unusual crying and rash, or gastrointestinal events)(2). Events in both groups were mostly mild or moderate reactions and transient, following a typical pattern of routine vaccinations(2).

Fever, which is a common event following routine childhood immunizations, was observed more frequently in infants who received the 4CMenB vaccine together with routine infant vaccines compared to infants receiving routine vaccines alone(2). Fever was generally low-grade, mild and of short duration, with 95 percent of cases resolving within 24-48 hours(2). These preliminary data findings will complement additional safety data that Novartis is evaluating as part of its complete phase III program.

Incidence of serious adverse events in infants who received 4CMenB with routine vaccines was comparable to those who received routine infant vaccines alone and those who received meningococcal C conjugate vaccine with routine infant vaccines(2). In the study, less than one percent of infants discontinued the trial due to reactogenicity following vaccination with no difference between groups(2).

Trial Design

This Phase III, randomized, controlled, multi-center study involved 3,630 healthy infants in trial sites throughout Europe. The primary endpoints of the study were to determine the consistency of

immune response to three lots of 4CMenB, and assess the immunogenicity and tolerability of three doses of 4CMenB (three lots combined) given concomitantly with routine infant vaccines.

The trial included an open-label immunogenicity and tolerability subset in which participants were randomized to receive one of three lots of 4CMenB vaccine with routine infant vaccines, or routine vaccines alone. Also included was an observer-blind safety subset in which participants were randomized to receive 4CMenB vaccine or meningococcal C conjugate vaccine with routine vaccines, or routine vaccines alone. Immunizations were administered at 2, 4, and 6 months of age. Primary immunogenicity was based on a serum bactericidal assay using human complement (hSBA) against three serogroup B strains (5/99, NZ98/254 and H44/76) 30 days after the final study vaccination. Injection site and systemic reactions were recorded for seven days post-vaccination, and adverse events were evaluated throughout the study(1), (2).

About 4CMenB Clinical Program

The entire 4CMenB Clinical program consists of clinical trials studying the immunogenicity, safety and tolerability of the investigational vaccine in four major age groups, including infants, toddlers, adolescents and adults worldwide. Results from a Phase II study in adults showed that 4CMenB generated an immune response and was generally well tolerated(13).

In addition, studies are under way to confirm the expected coverage of the broad-based vaccine against MenB strains circulating in several countries. The first results are expected prior to filing.

About Meningococcal Disease

Meningococcal disease is a leading cause of bacterial meningitis an infection of the membrane around the brain and spine and sepsis a bloodstream infection(14), (15), (16). Survivors may experience side effects, called sequelae, such as brain damage, learning disabilities, hearing loss and limb loss(16). Five main groups of meningococcal bacteria (A, B, C, W-135 and Y) cause the majority of all cases around the world(3).

Meningococcal disease caused by groups A, C, W-135 and Y is vaccine-preventable; however, MenB remains an unmet public health need as the most common cause of bacterial meningitis for which there is no readily available global vaccine(6). MenB also has been known to cause outbreaks of meningitis around the world, including New Zealand, the United Kingdom and Normandy, France(9), (17). Global incidence of MenB infection is estimated to be between 20,000 and 80,000 cases per year, with a 10 percent fatality rate(18).

About Novartis Vaccines global meningococcal franchise

Using a pioneering approach called reverse vaccinology Novartis has developed the investigational Multicomponent Meningococcal Serogroup B Vaccine (4CMenB). Novartis Vaccines also used innovative technology to produce Menjugate®, a meningococcal C conjugate vaccine approved outside the U.S. since 2000 for use in individuals from 2 months of age through adulthood, and Menveo®, a quadrivalent conjugate vaccine to help protect against four of the five major groups of meningococcal bacteria. In addition, Novartis also produced MeNZB®, a vaccine against a strain of meningococcus B specific to an outbreak in New Zealand. The company has already distributed more than 45 million doses of Menjugate around the world(19).

Novartis Vaccines is a global leader in providing vaccines to protect against deadly meningococcal disease. Through industry-leading scientific expertise, the company is focused on extending critical meningococcal vaccines research.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as could, potential, promise, can, expected, planned, promising, will or similar expressions, or by express or implied discussions regarding potential marketing approvals for 4CMenB, or the potential timing of such approvals, or regarding potential future revenues from 4CMenB. 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 4CMenB to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that 4CMenB will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that 4CMenB will achieve any particular levels of revenue in the future. In particular, management s expectations regarding 4CMenB 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; government, industry and general public pricing pressures; competition in general; 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 102,000 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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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Novartis AG

Date: September 12, 2010

By: /s/ MALCOLM B. CHEETHAM

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