

NOVARTIS AG  
Form 6-K  
February 25, 2010

# **SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

## **FORM 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 or 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**Report on Form 6-K dated February 22nd, 2010**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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**Form 20-F:** ☒ **Form 40-F:** ☐

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Yes: ☐ **No:** ☒

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**Novartis International AG**

Novartis Global Communications

CH-4002 Basel

Switzerland

<http://www.novartis.com>

**- Investor Relations Release -**

**Novartis receives FDA approval of Menveo®, a vaccine to prevent meningococcal disease**

- *Menveo licensed in 11-55 year olds to help protect against potentially deadly meningitis and sepsis caused by four common vaccine-preventable serogroups(1)*
- *Meningococcal disease causes approximately 50,000 deaths globally each year, many of which could be prevented through vaccines(2)*
- *Novartis plans to seek licensure of Menveo in infants and children 2-10 years of age*

**Basel, February 22, 2010** Novartis announced that Menveo® (Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine), a quadrivalent meningococcal conjugate vaccine was approved by the US Food and Drug Administration (FDA) for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135 in people 11 to 55 years of age(1).

Meningococcal disease infects more than 500,000 people each year, leading to more than 50,000 deaths globally(2). As many as 1 in 7 patients who contract meningococcal disease die from it(3). Approximately 1 in 5 meningococcal disease survivors suffer serious, permanent and devastating side effects, including limb amputations, seizures, paralysis, hearing loss and learning disabilities(4). Meningococcal disease is a leading cause of bacterial meningitis, which is an infection of the membrane around the brain and spinal cord, and sepsis, an often life-threatening bloodstream infection(4), (5). Even with early and appropriate treatment, the disease may progress rapidly and is potentially fatal, often within 24-48 hours of onset of symptoms(6).

The FDA approval of Menveo is an important milestone for adolescent immunization in the United States. According to CDC estimates, approximately 16 million adolescents between the ages of 11 and 18 are at risk and remain unprotected against meningococcal disease, said Andrin Oswald, Division Head of Novartis Vaccines and Diagnostics. Meningococcal disease is particularly distressing because it can rapidly kill or debilitate previously healthy adolescents. For this reason, we are dedicated to helping eradicate meningococcal disease in the United States and around the world.

In the United States, incidence of meningococcal disease varies, ranging between 1,000 and 3,000 cases per year(4).

FDA approval of Menveo was based on a Phase III head-to-head clinical trial that compared Menveo to the other US-licensed ACWY meningococcal conjugate vaccine among subjects 11 to 55 years of age. The trial, which was broken into two subsets – adolescents, age 11 to 18, and adults, age 19 to 55 – measured for each of the four serogroups both the percentage of subjects who achieved an immune response as measured by seroresponse and proportions

achieving human serum bactericidal antibody (hSBA) titers  $\geq 1:8$ . Additionally the study examined antibody level as measured by geometric mean titers (GMT)(1).

Even with early and appropriate treatment, patients can die from meningococcal disease, often within 24-48 hours of onset of symptoms(6). Menveo achieved a higher immune response than the other currently available vaccine, which is very reassuring, said Keith S. Reisinger, MD, Medical Director, Primary Physicians Research, Inc., Pittsburgh, Penn. With the FDA approval of Menveo, now healthcare providers in the United States have another option to help prevent this life-threatening invasive disease.

In study participants aged 11 to 18 years, Menveo met its primary endpoint for all four serogroups using hSBA seroresponse. The percentages of subjects who demonstrated an immune response (i.e., achieved an hSBA titer  $\geq 1:8$ ) for each serogroup for Menveo and its comparator (the other currently US-licensed ACWY meningococcal conjugate vaccine) respectively, were: Serogroup A 75: 67; serogroup C 84: 84; serogroup Y 88: 69; and serogroup W-135 96: 881.

The seroresponse with Menveo for serogroups A, Y and W-135, was statistically higher. However the clinical relevance of higher post-vaccination immune responses is not known.

In the same group, the levels of circulating antibodies (i.e., GMT) in those who received Menveo vs. those who received the comparator, respectively, were: Serogroup A 29: 18; serogroup C 59: 47; serogroup Y 51: 18; and serogroup W-135 87: 441.

Since 2005, the Advisory Committee on Immunization Practices, a group of 15 experts who advise the US Centers for Disease Control and Prevention (CDC) on the control of vaccine-preventable diseases, has recommended routine immunization with a quadrivalent meningococcal conjugate vaccine 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(3).

Approval of Menveo is the result of 10 years of dedicated effort by Novartis Vaccines to provide a vaccine that can help protect people against meningococcal disease. The Menveo development program for other age groups continues in multiple Phase III clinical trials. Menveo has the potential to be utilized in a broad age range, and the company plans to seek supplementary licensures for use of the vaccine in other age groups. Data to support an indication for children 2 to 10 years of age is expected to be submitted in the first half of 2010. Novartis expects to file data to support an infant indication in 2011.

About meningococcal disease, a leading cause of bacterial meningitis

Because invasive meningococcal disease can progress so rapidly, high levels of circulating antibodies are critical for protection. Immune memory typically takes up to five days to develop, so there often is not enough time for immune memory to mount a protective response once the disease has started(7).

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Five serogroups cause the majority of meningococcal disease worldwide: A, B, C, Y and W-135(8). Distribution of serogroups varies widely from geographic region to region and changes over time(8). Currently, in the United States, most disease is caused by serogroups B, C, and Y(3). The prevalence of serogroup Y has increased over the last few years (from 9 percent of reported cases in 1990 to 1992 to 39 percent in 2006)(7). Epidemiology of meningococcal disease is constantly changing(8), so it is impossible to determine which serogroups will result in the majority of disease cases year over year.

For more information, please visit [www.meningitis.com](http://www.meningitis.com).

About Novartis Vaccines global meningococcal franchise

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. In addition to developing Menveo vaccine, Novartis Vaccines is developing a recombinant vaccine for its potential to provide broad coverage against multiple strains of serogroup B, for which no vaccine is currently available.

Menveo vaccine is based on the same proprietary technology Novartis Vaccines pioneered to produce Menjugate®, a meningococcal serogroup C conjugate vaccine approved outside the US since 2000. The company has already distributed more than 41 million doses of Menjugate around the world and produced MenZB®, a vaccine against a strain of meningococcus B specific to a recent outbreak in New Zealand.

### 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. 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 a 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 all subjects who received Menveo were pain at the injection site, headache, myalgia, malaise, and nausea. Some events were severe. Safety has not been established in pregnant women. Vaccination with Menveo may not protect all individuals.

### Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potentially, could, plans, may, risk, dedicated, can, potential, plans, expected, expects, will, or similar expressions, or by express or implied discussions regarding potential indications or labeling for Menveo, potential future approvals of additional Novartis vaccines, or the timing of any such approvals or regarding potential future revenues from such vaccines. 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 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 approved for any additional indications or labeling in any market. Nor can there be any guarantee that any additional vaccines will be approved for sale in any markets. Neither can there be any guarantee that any such approvals will be obtained at any particular time. Nor can there be any guarantee that Menveo or any additional vaccines will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Menveo or any additional vaccines 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; 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 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 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 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

## References

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8. Schaffner, W. et al. The Changing Epidemiology of Meningococcal Disease Among US Children, Adolescents, and Young Adults. National Foundation for Infectious Diseases. November 2004.

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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

e-mail: media.relations@novartis.com

**Beth Birke**

Novartis Vaccines and Diagnostics

+1 (617) 871 4281 (direct)

+1 (617) 803 4359 (mobile)

nvd.communications@novartis.com

**Novartis Investor Relations**

**Central phone:**

Ruth Metzler-Arnold

Pierre-Michel Bringer

John Gilardi

Thomas Hungerbuehler

Isabella Zinck

+41 61 324 7944

+41 61 324 9980

+41 61 324 1065

+41 61 324 3018

+41 61 324 8425

+41 61 324 7188

e-mail: investor.relations@novartis.com

**North America:**

Richard Jarvis

Jill Pozarek

Edwin Valeriano

+1 212 830 2433

+1 212 830 2445

+1 212 830 2456

e-mail: investor.relations@novartis.com

**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: February 22nd, 2010

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
Title: Head Group Financial  
Reporting and Accounting