

NOVARTIS AG  
Form 6-K  
March 31, 2009

## 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 March 30, 2009

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

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Switzerland

(Address of Principal Executive Offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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Yes:  No:

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**- Investor Relations Release -**

**Ixiaro® receives FDA approval for the prevention of Japanese Encephalitis**

- *JE is a devastating disease that results annually in 10,000-15,000 deaths worldwide and is a potential threat for travelers to Asia<sup>(2)</sup>*
- *In clinical trials Ixiaro was well tolerated and has been shown to provide a protective immune response in up to 99% of subjects after only two doses<sup>(4)</sup>*
- *The vaccine will be marketed in the US by Novartis and is part of the strategic alliance between Novartis Vaccines and Intercell AG*

**Basel, March 30, 2009** The United States Food and Drug Administration has approved Ixiaro® vaccine for the prevention of Japanese Encephalitis (JE). The vaccine will be marketed in the US as Ixiaro by Novartis Vaccines. JE, a mosquito-borne flaviviral infection, is a devastating disease that results in 10,000-15,000 deaths annually<sup>(1),(2)</sup> and is a potential threat for travelers to Asia.

Ixiaro was developed to provide a well-tolerated, effective and convenient vaccine against JE, suitable for administration to travelers who wish to reduce their risk of acquiring the disease. A vaccine against Japanese Encephalitis has been available for travelers from the US, however its use has been limited by concerns over its safety profile and a recent announcement of discontinued production. Ixiaro has been shown to be as immunogenic as the currently licensed JE vaccine but with a better local tolerability profile and a more convenient dosing schedule.

Asia is now the second most popular travel destination globally, and travel to the region is expected to increase. JE is spread by mosquitoes, which makes it unpredictable. Vaccination is the most effective preventive measure against the disease, said Dr. Andrin Oswald, CEO of Novartis Vaccines and Diagnostics.

Ixiaro was developed by Intercell AG. Novartis and Intercell have a strategic alliance based on a shared vision of science in vaccines R&D. The alliance provides Novartis with the development and commercialization rights to Intercell's entire non-partnered early state vaccines pipeline.

Ixiaro received a positive opinion from the CHMP (European Committee for Human Medicinal Products) of the European Medicines Agency on the Marketing Authorization in December 2008. Further pediatric studies with the vaccine are planned.

**Ixiaro Pivotal Study Details**

A total of 5,102 subjects have participated in eight Ixiaro clinical trials.

A randomized, multicenter, observer-blinded Phase III study was conducted to evaluate the immunogenicity of two doses of Ixiaro compared to three doses of the currently licensed vaccine in healthy adults. The primary objective of the study was to demonstrate non-inferiority of Ixiaro to JE-Vax® in terms of immunogenicity at day 56. Secondary objectives included the safety and

local tolerability of both vaccines. Ixiaro was found to be highly immunogenic, resulting in protective antibody titers in 99% of subjects following two doses(4). The immune response following vaccination with Ixiaro was sustained at six months, with 95% of the 181 subjects maintaining protective antibody titers. Eighty-three percent (83%) of subjects still maintained protective antibody levels after one year(7).

In addition, a multicenter, randomized, double-blind Phase III study was conducted in 2675 healthy adults to assess the safety and tolerability of Ixiaro compared with placebo injections. Ixiaro was found to be well tolerated and no allergic reactions were observed. Ixiaro was found to have a similar safety profile to placebo and a statistically significantly better local tolerability profile than JE-Vax(5),(6).

#### **About Ixiaro Vaccine**

Ixiaro is indicated for active immunization against JE virus for persons 17 years of age and older. Ixiaro is a purified inactivated state-of-the-art JE vaccine that uses cell culture technology. It provides a good immune response while being well tolerated. It does not contain thiomersal, gelatin or any other stabilizers or preservatives in its formulation. The vaccine is provided as a ready-to-use liquid formulation in pre-filled syringes and is administered in two doses 28 days apart.

On June 13, 2006, Novartis and Intercell announced that Novartis Vaccines had obtained worldwide marketing and distribution rights to the vaccine with the exception of Australia, Korea, Japan and certain other Asian markets. Ixiaro complements the Novartis Vaccines portfolio of travel vaccines which includes: Rabipur®/RabAvert® vaccine, for pre and post exposure prophylaxis treatment against rabies; Typhoral L® vaccine, an oral typhoid vaccine and HAVpur® vaccine for the prevention of Hepatitis A.

#### **About Japanese Encephalitis (JE)**

Japanese Encephalitis (JE) disease is an acute inflammatory condition of the brain and spinal cord caused by the Japanese encephalitis virus (JEV). Most JE virus infections are mild (fever and headache) or without apparent symptoms, but approximately one in 300 infections results in severe disease characterized by rapid onset of high fever, headache, neck stiffness, disorientation, coma, seizures, spastic paralysis and death. The fatality rate is approximately 30% and as many as 50% of those who survive suffer from persistent neurological sequelae(2),(3). In areas where the JE virus is common, encephalitis occurs mainly in young children because older children and adults are likely to have acquired natural immunity (through infection) or have been vaccinated. JE is a leading cause of viral encephalitis in Asia with 30,000 to 50,000 clinical cases reported annually(3).

Japanese encephalitis virus is only transmitted by certain types of mosquitoes (most commonly *Culex tritaeniorhynchus*). These mosquitoes are usually found in rural rice-growing and pig farming regions of Asia, but can also be found at the outskirts of cities. The mosquitoes become infected by feeding on domestic pigs and wild birds that are infected with the Japanese encephalitis virus. Infected mosquitoes then transmit the Japanese encephalitis virus to other pigs and water birds and also to humans during feeding(8). The nature of the JE life cycle means it is not possible to eradicate JE.

The transmission of JE is linked to the seasonality of the mosquitoes in these areas. JE is transmitted seasonally in large areas of Asia, but in some locations may be transmitted year round. Many areas with tropical climates hold a potential for year round transmission and, elsewhere, peak periods of increased viral transmission follows monsoon seasons and irrigation associated with rice cultivation.



JE is highly prevalent in Asia. Approximately 3 billion people live in areas at risk of the disease. JE has occurred from the islands of the Western Pacific in the east to the Pakistani border in the west, and from Korea in the north to Papua, New Guinea in the south.

Novartis Vaccines is committed to educating travelers and healthcare providers about the risk of acquiring JE during travel and about protective modalities, including Ixiaro vaccine.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as to market, will, potential, expected, planned, committed, risk, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Ixiaro or regarding potential future revenues from Ixiaro. 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 Ixiaro to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Ixiaro will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that Ixiaro will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Ixiaro could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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 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 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, preventive vaccines, diagnostic tools, cost-saving generic pharmaceuticals, and consumer health products. Novartis is the only company with leading positions in these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 96,700 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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**References**

- (1) PATH. JE in depth. [http://www.path.org/projects/JE\\_in\\_depth.php](http://www.path.org/projects/JE_in_depth.php) 2008
- (2) Centers for Disease Control and Prevention. Travelers Health: Yellow Book; Chapter 4, Japanese Encephalitis. <http://www.cdc.gov/travel/yellowBookCH4-JapaneseEncephalitis.aspx> 2007
- (3) <http://cdc.gov/ncidod/dvbid/jencephalitis/facts.htm>
- (4) C Tauber, E. Kollaritsch, H. Korinel, M. et al. Safety and immunogenicity of a Vero-cell derived, inactivated Japanese encephalitis vaccine: a non-inferiority, Phase III, randomized control trial Lancet 370[9602], 1847-1853. 1-12, 2007
- (5) Tauber E, Kollaritsch H, von Sonnenburg F et al. Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial of the Safety and Tolerability of IC51, an Inactivated Japanese Encephalitis Vaccine. J Infect Dis 2008; 198:493-499
- (6) Dubuscgar-Kastner, K., Kaltenboeck, A., Schuller, E. et al. Six months Safety of a Vero-cell culture derived Japanese Encephalitis Vaccine, IXIARO, IC51, across Phase 3 trials and in a long term-follow up cohort. Abstracts of the 57th American Society for Tropical Medicine and Hygiene annual meeting, New Orleans, LA, USA, December 7-11, 2008
- (7) Schuller, E., Jilma, B., Voicu, V. et al. Long-term immunogenicity of the new Vero cell-derived, inactivated Japanese encephalitis virus vaccine IC51: six and 12 month results of a multicenter follow-up phase 3 study. Vaccine. 2008. Aug 12;26(34):4382-6
- (8) Solomon, T, Mallewa M. Dengue and other emerging flaviviruses. J Infect 2001;42:104-115

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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: March 30, 2009

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
Title: Head Group Financial  
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