

NOVARTIS AG  
Form 6-K  
April 06, 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 April 2, 2009

(Commission File No. 1-15024)

---

**Novartis AG**

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

---

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

Edgar Filing: NOVARTIS AG - Form 6-K

Form 20-F: **x**      Form 40-F: o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: o      **No: x**

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: o      **No: x**

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o      **No: x**

---

**Novartis International AG**

Novartis Global Communications

CH-4002 Basel

Switzerland

<http://www.novartis.com>

**- Investor Relations Release -**

**Ixiaro® vaccine receives Marketing Authorization in Europe for the prevention of Japanese Encephalitis**

- *First major achievement from strategic alliance between Novartis Vaccines and Intercell announced in 2006*
- *Ixiaro strengthens Novartis Vaccines travel portfolio which now includes vaccines against Japanese Encephalitis, rabies and tick-borne encephalitis*
- *Japanese Encephalitis is a potentially life-threatening disease for travelers from Europe to Asia*

**Basel, April 2, 2009** The European Commission has granted Marketing Authorization to Ixiaro® vaccine for the prevention of Japanese Encephalitis (JE). JE, a mosquito-borne flaviviral infection, results in 10,000-15,000 deaths annually<sup>(1),(2)</sup> and is a potentially life-threatening disease 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. Until now there has not been a licensed Japanese Encephalitis vaccine in Europe. JE is highly prevalent in Asia. It has occurred from the islands of the Western Pacific in the east to Pakistan in the west, and from far Eastern Russia and Korea in the north to Northern Australia in the south.

Asia is a very popular travel destination for Europeans. Since JE is spread by mosquitoes, the threat to travelers is unpredictable, said Dr. Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. Vaccination is the most effective preventive measure against the disease and Ixiaro will address an unmet medical need for travelers from Europe to Asia.

## Edgar Filing: NOVARTIS AG - Form 6-K

Ixiaro was developed by Intercell AG. Novartis and Intercell have a strategic alliance that provides Novartis with the commercialization rights to Ixiaro. On December 18, 2008, the Committee for Medicinal Products for Human Use (CHMP) recommended to grant marketing authorization to Ixiaro. The European Commission has granted marketing authorization for the 27 countries of the European Union, as well as Norway and Iceland. Ixiaro vaccine also has received marketing authorization in Australia and received FDA approval in the United States on March 30, 2009. 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 the US) in healthy adults.

The primary objective of the study was to demonstrate non-inferiority of Ixiaro to JE-Vax®(9) 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 2,675 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),(9).

### **About Ixiaro Vaccine**

Ixiaro is indicated for active immunization against JE virus for persons 18 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, protection 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 long term 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 areas 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. Approximately 3 billion people live in areas at risk of the disease. 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 potentially, will, planned, committed, awaiting, or similar expressions, or by express or implied discussions regarding potential new indications or marketing approvals 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 in any additional markets. 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.

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>.

---

## 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) Dubuscar-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
- (9) Produced by The Research Foundation for Microbial Diseases of Osaka University, BIKEN in Japan

###

## 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](mailto:eric.althoff@novartis.com)

### Paul Newman

Novartis Vaccines and Diagnostics  
+1 (617) 871-7931 (direct)  
+1 (617) 710-8953 (mobile)  
[paulc.newman@novartis.com](mailto:paulc.newman@novartis.com)

e-mail: [media.relations@novartis.com](mailto: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](mailto:investor.relations@novartis.com)

e-mail: [investor.relations@novartis.com](mailto: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: April 2, 2009

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial Reporting and Accounting