NOVARTIS AG
Form 6-K
June 14, 2006

# 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 June 13, 2006**
**(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:

**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

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**- Investor Relations Release -**

## Rasilez®(1) shows superior efficacy to ACE inhibitor ramipril in head-to-head study involving people with diabetes and high blood pressure(1,2)

- *Superior systolic blood pressure reductions with Rasilez monotherapy versus ramipril (ACE inhibitor) seen in study(1)*
- *Rasilez shows additive blood pressure reductions when used with ACE inhibitor(1)*
- *Sustained 24-hour blood pressure control with Rasilez when used alone or in combination with the ACE inhibitor ramipril*(2)
- *Direct renin inhibitors expected to become the first new treatment class for high blood pressure in more than 10 years*

**Basel, June 13, 2006** Newly-released clinical data show that Rasilez® (aliskiren), the first orally effective direct renin inhibitor, provided superior reductions in systolic blood pressure over the ACE inhibitor ramipril in people with diabetes and hypertension.(1)

The data, presented today at 16th Scientific Meeting of the European Society of Hypertension (ESH) in Madrid, also show that the combination of Rasilez and ramipril improved blood pressure control over the use of either medication alone.

Other information presented at ESH show that Rasilez provided sustained and persistent blood pressure reductions over 24 hours in people with diabetes.(2) Sustained 24-hour control is important because blood pressure often surges during early morning hours.

It is particularly important for people with both diabetes and high blood pressure to gain control over both of these diseases, said Dr. James Shannon, MD, Head of Development at Novartis Pharma AG. These new data demonstrate that using Rasilez in combination with commonly-used hypertension medicines, such as ramipril, can help patients achieve significantly better blood pressure control than with ramipril alone.

The US submission of Rasilez was completed in April 2006, while the European submission remains on track for the end of 2006.

High blood pressure, and its consequences, is the world s No. 1 killer, affecting one in four adults or approximately one billion people globally.(3) The risk of cardiovascular complications is two to four times higher in people with diabetes than those without the disease, so the International Diabetes Federation recommends tight blood pressure control.(4) Despite extensive use of current therapies, about 70% of people with high blood pressure and nearly 90% with both diabetes and high blood pressure have not reached their target blood pressure levels.(5,6)

(1) The tradename Rasilez® is currently pending regulatory, including FDA, approval.

People with diabetes and high blood pressure need stringent 24-hour blood pressure control, said Dr. Hans-Henrik Parving, MD, of the Steno Diabetes Center in Denmark. This study(2) showed that aliskiren enhanced renin system suppression and resulted in greater blood pressure reductions.

**About the trial**

This eight-week study involved 837 people with diabetes and high blood pressure. The results showed that Rasilez alone reduced mean sitting systolic blood pressure (MSSBP) by 14.7 mmHg compared to 12.0 mmHg with ramipril alone. However, adding aliskiren to ramipril lowered MSSBP by 16.6 mmHg, which was significantly more effective than ramipril alone ($p<0.005$). Also, responder rates the number of people reaching the goal for mean sitting diastolic blood pressure (MSDBP) were higher in people receiving aliskiren.(2)

The most common adverse events were cough and headache, whose frequencies were highest in the ramipril group (4.7% and 6.1%, respectively). Cough and headache were less commonly seen when aliskiren was added to ramipril (1.8% and 2.9%, respectively) than with ramipril alone.(2)

Throughout the clinical program, Rasilez at doses up to 300 mg (within the expected therapeutic dose range) has consistently shown tolerability similar to placebo. Rasilez has also been well tolerated when used with other common cardiovascular as well as anti-diabetic medicines.

**About Rasilez**

If approved, Rasilez, which was developed with Speedel, will represent the first new treatment approach for people with high blood pressure in more than a decade. It acts within the Renin System, which is central to blood pressure regulation. By directly inhibiting the Renin System s point of activation renin Rasilez decreases the system s activity, as measured by plasma renin activity (PRA).(7)

**Disclaimer**

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as expected to become can help , on track, if approved will , or similar expressions, or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Rasilez. Such statements reflect the current views of the Novartis group of companies with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Rasilez will be approved for sale in any market, or that it will reach any particular sales levels. In particular, management s expectations regarding the approval and commercialization of Rasilez could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data and new 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; increased government, industry, and general public pricing pressures; 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 (NYSE: NVS) is a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 96,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

**References**

1. Uresin Y, Taylor A, Kilo C, Tschope D, Santonastaso M, Ibram G, Fang H, Satlin A. Aliskiren, a novel renin inhibitor, has greater BP lowering than ramipril and additional BP lowering when combined with ramipril in patients with diabetes and hypertension. Poster to be presented at the 16th Scientific Meeting of the European Society of Hypertension. 2006.

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5. Hajjar I, Kotchen TA. Trends in prevalence, awareness, treatment, and control of hypertension in the United States, 1988-2000. *Journal of the American Medical Association.* 9 July 2003: 202.

6. American Diabetes Association. Diabetes & Cardiovascular Disease Review. Issue 2: Hypertension in Diabetes. Available at: http://www.diabetes.org/uedocuments/ADACardioReview_2.pdf. Accessed: 16/05/2006

7. Rasilez Prescribing Information Draft on file at Novartis.

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**- Investor Relations Release -**

**Novartis expands late-stage vaccines pipeline with novel vaccine for prevention of Japanese Encephalitis virus infections**

- *Novartis enters into agreement with Intercell AG to acquire marketing and distribution rights to IC51, a Phase III vaccine for prevention of Japanese Encephalitis virus infections with orphan status in Europe*

- *IC51 a novel second-generation vaccine with better tolerability over current prophylaxis for the leading cause of viral encephalitis in Asia*

- *Transaction underlines focus on vaccine innovation, with strong in-house activities complemented by strategic partnerships*

**Basel, June 13, 2006** Novartis announced today the expansion of its late-stage vaccines pipeline through an agreement to acquire marketing and distribution rights for IC51, a vaccine in Phase III clinical trials for the prevention of infections from the Japanese Encephalitis virus.

With this agreement, Novartis will gain the rights to the future commercialization of IC51, which received orphan status from the European regulatory agency earlier this year. Novartis has the rights to IC51 for the United States, Europe and certain other markets including Asia and Latin America, except for markets where Intercell has pre-existing agreements. Submission for US approval is anticipated to start in the second half of 2006. This vaccine will complement the company s offering of vaccines for travelers to endemic countries.

Novartis will make an equity investment in Intercell of up to EUR 30 million, which grants Novartis the first negotiation rights to certain existing product candidates derived from Intercell s technology, and also milestone payments related to IC51 for final Phase III data as well as US and EU regulatory approvals, which are assumed to occur in 2007 and 2008, respectively.

Novartis Vaccines is committed to disease prevention and strengthening its leadership position in human vaccines, said Dr. Jörg Reinhardt, CEO of Novartis Vaccines & Diagnostics. No effective treatment is currently approved to prevent the debilitating effects of Japanese Encephalitis, leaving an urgent need for new vaccines such as IC51. This agreement reinforces our commitment to develop innovative vaccines through our own development activities as well as strategic partnerships.

Japanese Encephalitis (JE) disease is an acute inflammatory condition of the brain and spinal cord caused by the Japanese Encephalitis virus (JEV), which is transmitted by mosquitoes that transmit the virus from infected animals, mostly domestic pigs, to humans at seasonal intervals. JE is a leading cause of viral encephalitis in Asia with 30,000 to 50,000 clinical cases reported annually.

**About IC51**

**About IC51**

IC51 is a second-generation JE vaccine that leverages cell culture technology with the aim of providing an effective but safer product compared to the currently available vaccine, which was developed in the 1950s and is made from a virulent strain of the JE virus (Nakayama strain) and propagated in mouse brains and then formulated with stabilizers and thimerosal.

IC51 is produced using an attenuated virus strain and mammalian cell culture technology. Formulation is completed with an adjuvant (aluminum hydroxide) to increase potency but without stabilizers and thimerosal.

This vaccine complements the Novartis portfolio of travel vaccines, which includes Encepur vaccine, a vaccine against tick-borne encephalitis (TBE); Rabipur®/RabAvert® vaccine, an effective pre-exposure and post-exposure prophylaxis treatment against rabies; Typhoral L vaccine, an oral typhoid vaccine; HAVpur vaccine, for the prevention of Hepatitis A; and Dukoral vaccine to prevent cholera.

**About Japanese Encephalitis**

Japanese encephalitis (JE) is a disease caused by a virus that affects the membranes around the brain. Most JE virus infections are mild (fever and headache) or without apparent symptoms, but approximately one in 200 infections results in severe disease characterized by rapid onset of high fever, headache, neck stiffness, disorientation, coma, seizures, spastic paralysis and death. According to the WHO, the fatality rate can be as high as 60% among those with disease symptoms; 30% of those who survive suffer from lasting damage to the central nervous system. In areas where the JE virus is common, encephalitis occurs mainly in young children because older children and adults have already been infected and are immune.

The virus is transmitted by mosquitoes that breed particularly in flooded rice fields. The virus circulates in birds such as herons and egrets. Pigs are amplifying hosts, in that the virus reproduces in pigs and infects mosquitoes that take blood meals, but does not cause disease.

Japanese encephalitis occurs 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. JE distribution is very significantly linked to irrigated rice production combined with pig rearing.

Immunization in Europe and the US is currently recommended for travelers who visit countries where JE is prevalent and stay there for more than four weeks, predominantly in rural areas. This restrictive recommendation is influenced by the fact that health care specialists are concerned about the safety of the currently available prevention options.

**Disclaimer**

This release contains certain forward-looking statements, relating to the Group s business, which can be identified by the use of forward-looking terminology such as is anticipated , will complement , will make , could amount to , the aim of , or by express or implied discussions regarding potential marketing approvals or future sales of IC51. Such statements reflect current views with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that IC51 will be approved for sale in any market or that it will reach any particular sales levels. Management s expectations regarding IC51 could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; 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; increased government, industry, and general public pricing pressures; and other risks and factors referred to in the Company s current Form 20-F on file with the U.S. 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 & Diagnostics is a new division of Novartis focused on the development of preventive treatments and tools. The division has two business units: Novartis Vaccines, and Chiron, the blood testing and molecular diagnostics unit. Novartis Vaccines is the world s fifth-largest vaccines manufacturer and second-largest supplier of flu vaccines in the US. Novartis Vaccines & Diagnostics products also include meningococcal, paediatric and travel vaccines. The Chiron business unit 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 (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 96,000 people and operate in over 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**

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| Date: June 13, 2006 | By: | /s/ Malcolm B. Cheetham |
| | Name: | Malcolm B. Cheetham |
| | Title: | Head Group Financial Reporting and Accounting |