NOVARTIS AG
Form 6-K
June 06, 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 6, 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

Enclosures:

1. Novartis launches global program expanding access to investigational compound nilotinib (AMN107) for patients with hard-to-treat leukemia (Basel, June 4, 2006)

2. Glivec® sets new treatment standard in chronic myeloid leukemia with high overall survival, increasing response and decreasing progression (Basel, June 3, 2006)

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- Investor Relations Release -

Novartis launches global program expanding access to investigational compound nilotinib (AMN107) for patients with hard-to-treat leukemia

New worldwide program addresses unmet medical need for patients with treatment-resistant Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML)

Nilotinib receives FDA fast track designation in US as well as orphan drug status in both the US and EU

US and EU regulatory submissions now planned for late 2006 compared to earlier expectations for 2007

Basel, June 4, 2006 Novartis announced today the launch of a global program, ENACT (Expanding Nilotinib Access in Clinical Trials), to provide expanded access to nilotinib (AMN107), a compound currently in late-stage registration trials for treating certain forms of the life-threatening disease leukemia.

This program is available to eligible patients in all phases of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) who are either resistant to or intolerant of treatment with Glivec® (imatinib)(1). Novartis is now planning to submit nilotinib for US and EU regulatory approval in late 2006 compared to earlier estimates for submissions in 2007.

(1) Known as Gleevec® (imatinib mesylate) Tablets in the US

ENACT is another example of our ongoing commitment to making innovative therapies available to patients who need new treatment options, said David Epstein, President of Novartis Oncology. With Glivec, Novartis launched a wide-ranging access program that enabled more than 9,000 patients around the world to obtain Glivec at no cost before it became commercially available. This program continues our dedication to patients by providing an option to those who are no longer responding to Glivec.

Information about ENACT can be found on the clinical trial website of the US National Institutes of Health, www.clinicaltrials.gov. Information is also available by contacting the Novartis local offices or local call center, which will refer requests to the appropriate clinical team. Physicians can access information at www.amn107.com.

About nilotinib

Nilotinib represents the next generation targeted, oral therapy specifically designed to be the most selective inhibitor of Bcr-Abl, the definite cause of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML), and its mutations. Designed in the biomedical research facilities of Novartis, nilotinib is a tyrosine kinase inhibitor with high affinity and specificity to attach itself to Bcr-Abl, the definitive cause of Ph+ CML, and 32 of 33 mutant forms most commonly associated with the disease.

The US Food and Drug Administration (FDA) has granted both fast track designation and orphan drug status to nilotinib. Nilotinib also received orphan drug status from the European Medicines Evaluation Agency (EMEA).

As an investigational compound, the safety and efficacy profile of nilotinib has not yet been established. Data from a Phase I clinical trial presented at the 2005 Annual Meeting of the American Society of Hematology (ASH) showed complete hematologic responses in 92% of patients in chronic phase, as well as hematologic responses in 76% of patients in accelerated phase and in 42% of patients in myeloid blast crisis. Cytogenetic responses were also seen in 53% of patients in chronic phase, 55% in accelerated phase and 29% in myeloid blast crisis.

Access to nilotinib is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the compound s potential benefits and risks and data will be filed with regulatory authorities such as the FDA and the EMEA for regulatory approval.

About Glivec

Glivec is approved in more than 90 countries including the US, EU and Japan for the treatment of all phases of Ph+ CML.

The effectiveness of Glivec is based on overall hematologic and cytogenetic response rates and progression-free survival in CML. There are no controlled trials demonstrating increased survival.

Glivec contraindications, warnings and adverse events(1)

The majority of patients treated with Glivec experienced adverse events at some time. Most events were of mild to moderate grade and treatment was discontinued for adverse events only in 2% of patients in chronic phase, 3% in accelerated phase and 5% in blast crisis. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, as well as neutropenia and thrombocytopenia.

(1) Numbers indicate the range in percentages in four studies among patients with CML in blast crisis, accelerated phase and chronic phase.

Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

The foregoing release contains forward-looking statements that can be identified by terminology such as planned, planning, will, or similar expressions, or by express or implied discussions regarding potential regulatory approvals of nilotinib or potential future sales of nilotinib, or regarding the long-term impact of a patient s use of nilotinib. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with nilotinib to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that nilotinib will be approved for sale in any market. Nor can there be any guarantee regarding potential future sales of nilotinib. Neither can there be any guarantee regarding the long-term impact of a patient s use of nilotinib. In particular, management s expectations regarding nilotinib could be affected by, among other things, unexpected clinical trial results, including new clinical data, and additional analysis of existing nilotinib 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; 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 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 this information as of this date and does not undertake any obligation to

update any forward-looking statements contained in this document 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.

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- Investor Relations Release -

Glivec® sets new treatment standard in chronic myeloid leukemia with high overall survival, increasing response and decreasing progression

Nearly 90% of patients with Philadelphia chromosome-positive CML alive at five years with new analysis showing less than 5% mortality due to CML

Response rate to Glivec increases substantially over five years in landmark IRIS study, the largest ever conducted in CML patients

Yearly rate of progression to more advanced disease continues to drop the longer patients take Glivec, falling to 0.6% in fifth year

Basel, June 3, 2006 Response rates to Glivec® (imatinib)* continue to increase substantially over time while the yearly risk of progression to advanced disease continues to decline the longer patients take the medicine, according to five-year data from a landmark study in patients with a form of life-threatening chronic myeloid leukemia.

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* Known as Gleevec® (imatinib mesylate) tablets in the US

Results of the International Randomized Interferon versus STI571 (IRIS) were presented today at the 2006 Annual Meeting of the American Society of Clinical Oncology.

Data from the IRIS study, the largest clinical trial to date for newly diagnosed adult patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, showed the overall survival rate at five years to be 89.4% (range 86% to 92%) for patients receiving Glivec. This considers deaths from all causes, but only 4.6% of the patients died from causes related to their leukemia. Before Glivec

was available, about 50% of patients progressed to the more advanced stages of Ph+ CML after only three to five years, and survival was generally short for those patients.

The results of this Phase III trial, which was started in June 2000, also showed that the number of patients with a complete cytogenetic response increased from 69% to 87% between the first and fifth years of treatment. Moreover, the yearly risk of progressing to advanced disease continued to decline to 0.6% in the fifth year.

Very few oncology medicines offer patients the opportunity to achieve better outcomes the longer they take the therapy, said David Epstein, President of Novartis Oncology. That Glivec demonstrates these significant improvements with long-term use is a good sign science will provide the path to turn lethal cancers into potentially manageable conditions with durable, well-tolerated targeted therapies.

An estimated 93% of Glivec patients in the early, chronic phase of CML did not progress to the rapidly lethal advanced stages of the disease, and an estimated 83% survived with no evidence of disease progression at all at the five-year follow-up.

IRIS study details

The International Randomized Interferon versus STI571 (IRIS) study is an open-label Phase III clinical trial enrolling 1,106 newly diagnosed patients with Ph+ CML in chronic phase in 177 centers across 16 countries. There are two arms to the study: one group of patients receiving Glivec 400 mg per day and another receiving a target dose of interferon (IFN) of 5 MIU/m2/day in combination with Ara-C 20 mg/m2/day for 10 days each month. Because of tolerability reasons or lack or loss of response to treatment, 69% of patients in the IFN/Ara-C arm crossed over to the Glivec arm, whereas only 3% of patients in the Glivec arm crossed over to the IFN/Ara-C arm.

Cumulative best responses to Glivec treatment improved significantly between the first and fifth years of treatment. Over the period, complete hematologic responses rose from 96% to 98%, major cytogenetic responses rose from 85% to 92% and complete cytogenetic responses rose from 69% to 87%.

In a complete hematologic response, the patient s blood cell counts return to normal. Cytogenetic response refers to the disappearance or reduction of the number of Ph+ cells detectable by standard lab methods.

Glivec continued to be generally well tolerated as initial drug therapy for Ph+ CML at the five-year follow-up. See Glivec contraindications, warnings and adverse events for details.

About Glivec

First launched in 2001 and now available in more than 80 countries, Gleevec is a signal transduction inhibitor approved to treat Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML). It is one of the first oncology drugs that validate rational drug design based on an understanding of how some cancer cells work. This product, known as Gleevec in the US and as Glivec in other markets, is approved in more than 90 countries including the US, EU and Japan for the treatment of all phases of Ph+ CML.

The effectiveness of Glivec is based on overall hematologic and cytogenetic response rates and progression-free survival in CML. There are no controlled trials demonstrating increased survival.

Glivec contraindications, warnings and adverse events*

The majority of patients treated with Glivec experienced adverse events at some time. Most events were of mild to moderate grade and treatment was discontinued for adverse events only in 2% of patients in chronic phase, 3% in accelerated phase and 5% in blast crisis. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, as well as neutropenia and thrombocytopenia.

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Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

The foregoing release contains forward-looking statements that can be identified by terminology such as increases substantially over five years, Yearly rate of progression, increase substantially over time, yearly risk of progression to advanced disease, long-term use, will, or similar expressions, or by express or implied discussions regarding potential future sales of Glivec, or regarding the long-term impact of a patient s use of Glivec. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no

guarantee that Glivec will achieve any particular levels of sales. Neither can there be any guarantee regarding the long-term impact of a patient s use of Glivec. In particular, management s expectations regarding Glivec could be affected by, among other things, unexpected clinical trial results, including new clinical data, and 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; competition in general; 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 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 this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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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: June 6, 2006

By: /s/ MALCOLM B. CHEETHAM
Name: Malcolm B. Cheetham
Title: Head Group Financial Reporting and Accounting