NOVARTIS AG
Form 6-K
June 16, 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

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

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:

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

Investor Relations

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- Investor Relations Release -

Patients with treatment-resistant leukemia achieve high responses to Tasigna® (nilotinib) in first published clinical trial results

New England Journal of Medicine publishes first evaluation of Tasigna, a promising next-generation targeted therapy, five years after issuing historic Glivec® Phase I data

Tasigna designed to be a highly selective inhibitor of Bcr-Abl, the definitive cause of Ph+ CML, and its mutations

More than 90% of patients with an unresponsive form of chronic myeloid leukemia (CML) in chronic phase treated with Tasigna achieved normal blood cell counts in less than five months

Basel, June 14, 2006 The first-ever published clinical trial data about the investigational drug Tasigna® (nilotinib) showed the compound helped more than 90% of patients diagnosed with an unresponsive form of leukemia, a life-threatening disease.

The data were published today in the *New England Journal of Medicine.*

In less than five months of treatment, 92% of patients with chronic phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) achieved a complete hematologic response with normal white blood cell counts after having shown resistance or intolerance to optimized Glivec® (imatinib)(1) therapy.

In more than a third of these patients, the Ph chromosome, the genetic abnormality that characterizes most cases of CML, was undetectable after treatment with Tasigna, as measured by standard laboratory methods. A total of 106 patients with Ph+ CML participated in this study: 33 patients in blast crisis, 56 patients in accelerated phase, and 17 patients in chronic phase. In addition, 13 patients with Ph+ acute lymphoblastic leukemia were included in the study.

Both Tasigna and Glivec inhibit Bcr-Abl, the definitive cause of Ph+ CML in effect, shutting down production of the Ph chromosome. Tasigna was specifically designed to be a more selective inhibitor of Bcr-Abl and its mutations, which can cause resistance to treatment.

By selectively inhibiting Bcr-Abl and its common mutations, Tasigna produced dramatic positive responses in patients who had limited treatment options, said Hagop Kantarjian, MD, Professor of Medicine and Internist, Chair, Department of Leukemia, M.D. Anderson Cancer Center. These extremely

(1) Known as Gleevec® (imatinib mesylate) tablets in the U.S.

encouraging results reinforce the validity of treating this cancer by specifically targeting the one protein known to cause the disease.

Patients in the most advanced phases of CML responded to Tasigna therapy. The overall rate of hematologic response (normalization of white blood cell counts) for patients in accelerated phase was 72% and the rate of cytogenetic response (reduction or elimination of the Ph+ chromosome) was 48%. Among patients in blast crisis, the response rates were 39% and 27%, respectively.

The study investigators concluded that Tasigna was generally well tolerated. Common adverse events included myelosuppression, transient indirect hyperbilirubinemia and skin rashes. Additionally, the investigators noted that Tasigna was usually not associated with common toxicities seen with Glivec (e.g. fluid retention, superficial edema, weight gain), or rare cases of pleural and pericardial effusions.

About Tasigna

Discovered in the biomedical research facilities of Novartis, Tasigna (investigational name AMN107) entered Phase I clinical studies just 21 months after it was first synthesized. It is a next generation tyrosine kinase inhibitor in Ph+ CML with a high affinity and specificity to attach itself to Bcr-Abl and to 32 of 33 mutant forms commonly associated with Ph+ CML. The U.S. Food and Drug Administration (FDA) has granted both fast track designation and orphan drug status to Tasigna. Tasigna also received orphan drug status from the European Medicines Agency (EMEA). Novartis is now planning to submit Tasigna for US and EU regulatory approval in late 2006 compared to earlier estimates for submissions in 2007.

As an investigational compound, the safety and efficacy profile of Tasigna has not yet been established. Access to Tasigna 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 U.S. FDA and the European Medicines Agency 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(2)

In the first-line study (IRIS), the safety profile with Glivec was similar to that of previous Phase II studies in other CML patients. 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.

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 promising, extremely encouraging results, planning, will be filed, or similar expressions, or by express or implied discussions regarding potential regulatory submissions or approvals of Tasigna, potential future sales of Tasigna or Glivec, or regarding the long-term impact of a patient s use of Tasigna or Glivec. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Tasigna and Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that

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

Tasigna will be approved for sale in any market. Nor can there be any guarantee regarding potential future sales of Tasigna or Glivec. Neither can there be any guarantee regarding the long-term impact of a patient s use of Tasigna or Glivec. In particular, management s expectations regarding Tasigna and 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.

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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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 15, 2006

By: /s/ MALCOLM B. CHEETHAM

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