NOVARTIS AG
Form 6-K
December 07, 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 December 7, 2006

(**Commission File No.** 1-15024)

Novartis AG

(Name of Registrant)

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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

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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

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- Investor Relations Release -

Glivec® demonstrates highest five-year overall survival rate in history of treatment for patients with chronic myeloid leukemia

- *New England Journal of Medicine article cites overall survival found to be 95% after excluding causes of death unrelated to CML or prior bone marrow transplantation*
- *Glivec results improve with long-term use percentage of patients with no trace of disease-causing Philadelphia chromosome increased dramatically in fifth year of study*
- *Long-term data confirm Glivec as a generally well-tolerated therapy with manageable safety profile*

Basel, December 6, 2006 Data published today in the *New England Journal of Medicine* underpinned Glivec® (imatinib)* as a durable and well-tolerated long-term therapy for newly diagnosed adult patients with a form of blood cancer known as Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML).

According to the publication, the five-year overall survival of patients who received Glivec as initial therapy is higher estimated at 95% when excluding deaths from causes unrelated to CML or prior transplantation than that in any previously published prospective study of the treatment of CML, a disease with limited survival options before the approval of Glivec.

Results of the International Randomized Interferon versus STI571 (IRIS) study the largest clinical trial ever for this patient population showed that responses to therapy with Glivec continued to increase substantially over five years, while the yearly risk of progression to advanced disease declined to 0.6% in the fifth year.

These data underscore that Glivec continues to support positive outcomes in CML with the opportunity for patients to achieve better outcomes the longer they take the therapy, said David Epstein, president and CEO of Novartis Oncology. The five-year data also show that Glivec offers very good tolerability as well as an established and predictable safety profile.

The overall survival rate for patients receiving Glivec was 89% (range 86% to 92%) when considering deaths from all causes. However, when deaths from causes unrelated to CML or prior transplantation are excluded, the overall survival rate was 95% at 60 months.

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.

Glivec has continued to be generally well-tolerated as initial drug therapy for Ph+ CML in chronic phase at the five-year follow-up. With a median follow up of 60 months, the adverse events were similar to the previously reported profile. Newly occurring or worsening grade 3 or 4 hematologic or biochemical adverse events were infrequent after two and four years of therapy.

Most recently, Glivec was approved in the European Union (EU) for the treatment of patients with the rare life-threatening blood disorders myelodysplastic syndromes/myeloproliferative diseases (MDS/MPD) and hypereosinophilic syndrome/chronic eosinophilic leukemia (HES/CEL). Glivec was also recently approved in the EU for adult patients with newly diagnosed Ph+ acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy and as a single agent for patients with relapsed or refractory Ph+ ALL, and in the US for relapsed/refractory Ph+ ALL.

In only five years, Glivec has now been approved in the EU for six diseases, including two solid tumors and four blood disorders with molecular targets known to be inhibited by the drug. In the US, Glivec has now been approved for seven diseases, including two solid tumors and five blood disorders with molecular targets known to be inhibited by the drug.

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, lack of response, or loss of response, 65% 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 dramatically between the first and fifth years of treatment. Over the period, major cytogenetic responses rose from 85% to 92% and complete cytogenetic responses rose from 69% to 87%. Complete hematologic responses rose from 96% to 98%. 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.

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. Glivec is also approved in the EU, US and other countries for the treatment of patients with Kit (CD117)-positive gastrointestinal tumors (GIST), which cannot be surgically removed and/or have already spread to other parts of the body (metastasized). In Japan, Glivec is approved for the treatment of patients with Kit (CD117)-positive GIST.

In the EU, Glivec is also approved for the treatment of adult patients with newly diagnosed Ph+ acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy and as a single agent for patients with relapsed or refractory Ph+ ALL, and for the treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) who are not eligible for surgery.

The effectiveness of Glivec is based on overall hematologic and cytogenetic response rates and progression-free survival in CML, on hematological and cytogenetic response rates in Ph+ ALL, and on objective response rates in GIST and DFSP. There are no controlled trials demonstrating increased survival.

Glivec contraindications, warnings and adverse events

The majority of patients treated with Glivec in clinical trials experienced adverse events at some time. Most events were of mild to moderate grade and treatment discontinuation was not necessary in the majority of cases.

The safety profile of Glivec was similar in all indications. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, abdominal pain, myalgia, arthralgia, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, dermatitis, eczema, fluid retention, as well as neutropenia, thrombocytopenia and anemia. Glivec was generally well-tolerated in all of the studies that were performed, either as monotherapy or in combination with chemotherapy, with the exception of a transient liver toxicity in the form of transaminase elevation and hyperbilirubimaemia observed when Glivec was combined with high dose chemotherapy.

Patients with cardiac disease or risk factors for cardiac failure should be monitored carefully and any patient with signs or symptoms consistent with cardiac failure should be evaluated and treated. Cardiac screening should be considered in patients with HES/CEL, and patients with MDS/MPD or SM with high level of eosinophils (echocardiogram, serum troponin level).

Rare/serious adverse reactions include: sepsis, pneumonia, depression, convulsions, cardiac failure, thrombosis/embolism, ileus, pancreatitis, hepatic failure, exfoliative dermatitis, angioedema, Stevens-Johnson syndrome, renal failure, fluid retention, edema (including brain, eye, pericardium, abdomen and lung), hemorrhage (including brain, eye, kidney and gastrointestinal tract), diverticulitis, gastrointestinal perforation, tumour hemorrhage/ necrosis, hip osteonecrosis/avascular necrosis.

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.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as estimated , opportunity , or similar expressions, or by express or implied discussions regarding regarding the long-term impact of a patient s use of Glivec or potential future sales 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 regarding the long-term impact of a patient s use of Glivec. Nor can there be any guarantee regarding potential future sales of Glivec. In particular, management s expectations regarding Glivec could be affected by, among other things, unexpected clinical trial results, including additional analysis of Glivec 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; 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 99,000 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: December 7, 2006

By: /s/ Malcolm B. Cheetham

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