NOVARTIS AG
Form 6-K
December 12, 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 12, 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

Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

hppt://www.novartis.com

- Investor Relations Release -

Pivotal submission data shows Tasigna® achieved impressive response rates in chronic myeloid leukemia patients no longer helped by Glivec®

- *New data support US and EU submissions of next-generation targeted therapy offering hope to patients with resistance or intolerance to Glivec*

- *Tasigna shown to have impressive efficacy and manageable safety profile, with patients intolerant to Glivec rarely experiencing same side-effects on Tasigna*

- *About one of two patients treated with Tasigna had significantly reduced or no presence of cells with the defective chromosome that causes this blood cancer*

Basel, December 11, 2006 - New clinical data presented today demonstrated that Tasignaâ (nilotinib) eliminated or significantly reduced the presence of blood cells containing a defective chromosome in approximately half of adult patients with a form of life-threatening leukemia who developed resistance or intolerance to treatment with Glivec® (imatinib) *.

The reductions achieved in these patients resistant to Glivec, one of the first oncology drugs developed based on an understanding of how some cancer cells work, may be the highest ever reported with a targeted therapy at a minimum of six months follow-up.

The Phase II data, which forms the basis for US and EU regulatory submissions completed earlier in 2006, showed that the use of Tasigna in patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) reduced or eliminated the presence of this defective chromosome in 51% of Glivec-resistant patients in chronic phase of this disease and led to normalized white blood cell counts in 74% of these patients.

The study also showed a similar magnitude of elimination or reduction of these defective cells in 55% of intolerant patients. Data from this trial were presented today at the American Society of Hematology annual meeting.

Novartis has filed applications with both the US Food and Drug Administration (FDA) and European Medicines Agency (EMEA) for Tasigna as a therapy for adult patients with chronic or accelerated phase Ph+ CML with intolerance and/or resistance to Glivec.

* Known as Gleevec® (imatinib mesylate) tablets in the U.S., Canada and Israel

Tasigna was developed by Novartis as a next-generation targeted therapy based on the success of Glivec. Although data from the landmark IRIS trial - the largest-ever conducted in CML patients - demonstrated that nearly 90% of chronic-phase Ph+ CML patients taking Glivec were alive at five years, a small subset of patients develop resistance or cannot tolerate this therapy.

Both Tasigna and Glivec are designed to inhibit production of cells containing the Philadelphia chromosome by inhibiting the Bcr-Abl protein. Bcr-Abl is recognized as the key cause and driver of the proliferation of white blood cells that characterizes Ph+ CML.

While Tasigna and Glivec target the same pathways, the strategy behind the Tasigna research program was to design a preferentially Bcr-Abl targeted therapy that would be more potent against Glivec mutations but avoid the potential side effects of less targeted agents.

These exciting data demonstrate that Tasigna has the potential to offer a compelling new treatment option for patients with Ph+ CML. Designing Tasigna to be an even more targeted Bcr-Abl inhibitor than Glivec appears to be providing impressive efficacy results with a manageable safety profile, said David Epstein, CEO and President of Novartis Oncology. We look forward to further exploring the potential benefits of Tasigna through our broad Phase III clinical trial program in earlier CML settings.

Study details

The open-label Phase II study was designed to evaluate the safety and efficacy, as defined by hematologic (normalization of white blood cell counts) and cytogenetic (reduction or elimination of the Ph+ chromosome) response rates of Tasigna administered to Glivec-resistant or intolerant patients with Ph+ CML in chronic phase and accelerated phase. The 316 chronic-phase patients in the Phase II study were heavily pre-treated for Ph+ CML, with a significant majority (72%) having received at least 600 mg of Glivec as well as having been treated earlier with interferon (65%) and hydroxyurea (83%).

Among 279 assessable patients (i.e., those patients with at least six months of follow up) with chronic-phase disease, major cytogenetic response was observed in 145 (52%) of which 96 (34%) were complete. Complete hematologic response was reported in 137 (74%) of 185 assessable patients. In patients with at least 10 months follow up, the median time to cytogenetic response was 2.8 months (range 1 to 11), and the median time to complete hematologic response was 1.0 (range 1 to 8) months.

Among 64 patients with accelerated-phase disease, major cytogenetic response was observed after at least eight months follow-up in 23 (36%), of which 14 (22%) were complete. Confirmed hematologic response occurred in 38 (59%), of which 15 (23%) were complete. The median time to cytogenetic response was 2.0 months (range 1 to 8), and the median time to complete hematologic response was 1.0 (range 1 to 3) months.

The Phase II study showed an acceptable tolerability profile with a low incidence of events related to fluid retention such as edema, a side effect common with other tyrosine kinase inhibitors. The most frequent Grade 3 or 4 adverse events were primarily hematological in nature and include neutropenia and thrombocytepenia. Elevations were seen in bilirubin, liver function tests, lipase enzymes and blood sugar, which were mostly transient and resolved over time. These cases were easily managed and rarely led to discontinuation. Pancreatitis was reported in less than 1% of cases.

The study also showed virtually no non-hematologic cross-intolerance between Glivec and Tasigna. (Cross-intolerance occurs when patients cannot tolerate two different drugs because of the same side effects.) Causes of non-hematologic intolerance to Glivec, which occurred in 95 patients, included Grade 3 or 4 rash/skin toxicity, fluid retention, gastrointestinal intolerance, liver toxicity, and myalgia/arthralgia. When treated with Tasigna, none of these patients experienced

severe rash/skin toxicity, fluid retention or myalgia/arthralgia. One patient each experienced severe gastrointestinal intolerance and liver toxicity.

About Tasigna

Discovered in the biomedical research facilities of Novartis, Tasigna (nilotinib, formerly AMN107) entered Phase I clinical studies in 2004 just 21 months after it was first synthesized in August 2002.

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 has been filed with regulatory authorities.

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. Glivec is also approved for the treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) who are not eligible for surgery. Glivec is also approved for the treatment of patients with myelodysplastic/myeloproliferative diseases (MDS/MPD). Glivec is also approved for hypereosinophilic syndrome and/or chronic eosinophilic leukemia (HES/CEL).

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 hyperbilirubinemia observed when Glivec was combined with high dose chemotherapy.

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, tumor hemorrhage/ necrosis, hip osteonecrosis/avascular necrosis.

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 with high level of eosinophils (echocardiogram, serum troponin level).

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 offering hope, may be, strategy, would be, potential, appears to be, look forward to further exploring, potential benefits, designed to, or similar expressions, or by express or impli discussions regarding potential new regulatory approvals for Tasigna or potential future sales of Glivec or Tasigna, or regarding the long-term impact of a patient s use of Glivec or Tasigna. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec or Tasigna to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Tasigna will be approved for any indications in any market. Nor can there be any guarantee regarding potential future sales of Glivec or Tasigna. Neither can there be any guarantee regarding the long-term impact of a patient s use of Glivec or Tasigna. In particular, management s expectations regarding Glivec and Tasigna could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including additional analysis of clinical data, or new clinical data; competition in general; government, industry, and general public pricing pressures; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; 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.

# # #

Media Relations

Corinne Hoff

Novartis Global Media Relations

+41 61 324 9577 (direct)

+41 61 324 2200 (main)

corinne.hoff@novartis.com

Geoff Cook

Novartis Global Public Relations

+1 973 652 7927 (direct)

geoffrey.cook@novartis.com

e-mail: media.relations@novartis.com

Investor Relations

International

Ruth Metzler-Arnold	+41 61 324 7944
Katharina Ambühl	+41 61 324 5316
Nafida Bendali	+41 61 324 3514
Jason Hannon	+41 61 324 2152
Richard Jarvis	+41 61 324 4353
Silke Zentner	+41 61 324 8612

North America

Ronen Tamir	+1 212 830 2433
Arun Nadiga	+1 212 830 2444
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+1 212 830 2456

e-mail: 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: December 12, 2006

By: /s/ MALCOLM B. CHEETHAM

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