NOVARTIS AG
Form 6-K
October 24, 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 October 20, 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

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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 -

Glivec® approved in the US for five rare life-threatening disorders with limited treatment options

- ***Approvals represent the first time a regulatory authority has simultaneously approved one targeted medicine for five disorders***
- ***Now approved for the solid tumor cancer, dermatofibrosarcoma protuberans***
- ***US approval also granted for treatment of four blood diseases:***
- ***Relapsed/refractory Philadelphia chromosome-positive acute lymphoblastic leukemia***
- ***Myelodysplastic/myeloproliferative diseases***
- ***Hypereosinophilic syndrome/chronic eosinophilic leukemia***
- ***Aggressive systemic mastocytosis***
- ***Multiple approvals in only five years highlight new approach of developing treatments based on common molecular pathways***

Basel, October 20, 2006 In another important milestone, Glivec® (imatinib)(1) has received US regulatory approval to help patients with five distinct and potentially life-threatening disorders, representing the first time that a regulatory authority has ever simultaneously approved one targeted medicine for so many disorders.

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

All of the diseases covered in the new approval by the US Food and Drug Administration (FDA) are rare and potentially life threatening. For many of the patients who suffer from them, few if any approved treatments were available prior to Glivec.

The effectiveness of Glivec in these five diseases further underscores how cancers and diseases of different origin and location can share common pathways that often respond to the same targeted treatment, said Diane Young, MD, Vice President and global head of Clinical Development at Novartis Oncology. These approvals further build and demonstrate our historical commitment to developing

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

therapies for patients with rare diseases such as acromegaly, carcinoid syndrome and gastrointestinal stromal tumors.

The FDA approvals are based on data from Novartis-sponsored clinical studies and clinical data from independent medical researchers showing the efficacy of Glivec in treating these diseases, in which there is a suggested connection between a Glivec-sensitive pathway and the disease.

Glivec targets the activity of proteins called tyrosine kinases that appear to play important roles within some cancer cells. Glivec has been shown to inhibit the function of the tyrosine kinase Bcr-Abl in patients with certain forms of blood cancer Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) and Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) and the receptor tyrosine kinase Kit in Kit-positive GIST (gastrointestinal stromal tumor).

Researchers have found Glivec also inhibits other tyrosine kinases, including platelet-derived growth factor receptor (PDGFR), which have been shown to be activated in disease pathways that underlie a number of rare hematologic diseases, as well as some solid tumors.

The new diseases for which Glivec received approval include one solid tumor and various rare blood disorders. The solid tumor is dermatofibrosarcoma protuberans (DFSP), a type of tumor that begins as a hard lump found in the skin of the chest, abdomen or leg. The four blood diseases include:

- Relapsed/refractory Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL), a rapidly progressive blood cancer characterized by the presence of the Philadelphia chromosome

- Certain forms of myelodysplastic/myeloproliferative diseases (MDS/MPD), which involve certain blood cells made in the bone marrow

- Hypereosinophilic syndrome/chronic eosinophilic leukemia (HES/CEL), which is characterized by the persistent overproduction of eosinophils, a certain type of white blood cell

- Aggressive systemic mastocytosis (ASM), which is marked by the presence of too many mast cells, a certain type of white blood cell.

An approval for newly diagnosed adult patients is still under review by the FDA. In the European Union (EU), Glivec was recently approved for treatment of certain patients with Ph+ ALL as well as for adult patients with a form of DFSP. The EU is also reviewing applications for approval of Glivec as a treatment for the three other diseases MDS/MPD, HES/CEL and ASM.

About Glivec

In addition to the new indications in the US, Glivec is approved in more than 90 countries including the US, EU and Japan for the treatment of all phases of Ph+ chronic myeloid leukemia (CML). Glivec is also approved in the EU, US and other countries for the treatment of patients with Kit (CD117)-positive gastrointestinal tumors (GISTs), 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 GISTs. 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 events2

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.

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 commitment, potentially, or similar expressions, or by express or implied discussions regarding potential new indications for Glivec or 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 be approved for any additional indications in any market. Nor can there be any guarantee regarding potential future sales of Glivec. 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 additional analysis of existing Glivec clinical data and new clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; 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: October 20, 2006

By: /s/ MALCOLM B. CHEETHAM

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