NOVARTIS AG
Form 6-K
July 31, 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 July 28, 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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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Glivec® receives positive European Union opinion for treatment of rare, potentially life-threatening cancers with limited treatment options

- *CHMP scientific advisory committee supports use of Glivec in two additional diseases shown to be sensitive to the drug s molecular targets*

- *Innovative approach to improve access to multiple rare diseases*

Basel, July 28, 2006 - Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) has issued a positive opinion for the use of Glivec® (imatinib)* as a treatment for the solid tumor dermatofibrosarcoma protuberans (DFSP) and for hematologic malignancy Philadelphia chromosome-positive (Ph+) acute lymphocytic leukemia (ALL).

The committee s recommendation will now be considered by the European Commission, which is expected to issue a final decision within the coming months. The European Commission generally follows the recommendations of the scientific committee in its decisions.

Submissions for three other rare diseases - myeloproliferative disorders (MPD), hypereosinophilic syndrome (HES) and systemic mastocytosis (SM) - remain under review by the committee. Applications for marketing authorization of Glivec as a treatment for all five diseases have been submitted to and are currently under review by the US Food and Drug Administration. Glivec is already approved for the treatment of adult patients in all phases of Ph+ chronic myeloid leukemia (CML) and for patients with unresectable and/or metastatic Kit (CD117)-positive gastrointestinal stromal tumors (GIST).

Both DFSP and Ph+ ALL are rare and potentially-life threatening diseases. Few, if any, approved treatments are available for many patients suffering from these diseases. DFSP is a type of tumor that begins as a hard lump found in the skin of the chest, abdomen or leg. Ph+ ALL is a rapidly progressive and life threatening blood cancer.

We are now finding that cancers and diseases of different origin and location can share common pathways that often respond to the same targeted treatment, said Diane Young, vice president and global head of Clinical Development at Novartis Oncology. The positive CHMP opinion is hopeful news for patients who suffer from these rare diseases and have limited treatment options.

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 Ph+ CML and Ph+ ALL, and the receptor tyrosine kinase Kit in

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

Kit (CD117)-positive GIST. Researchers have found that 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 positive opinion was based on data from Novartis-sponsored clinical studies and clinical data from independent medical researchers showing efficacy of Glivec in the treatment of these diseases, in which there is a suggested connection between a Glivec-sensitive pathway and a disease.

About Glivec

Glivec is approved in more than 90 countries including the EU, US 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 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.

The effectiveness of Glivec is based on overall hematologic and cytogenetic response rates and progression-free survival in Ph+ CML, and objective response rates in Kit (CD117)-positive GISTs. There are no controlled trials demonstrating increased survival.

Glivec contraindications, warnings and adverse event

The most common undesirable effects are: headache, nausea, vomiting, diarrhea, dyspepsia, abdominal pain, myalgia, arthralgia, muscle spasm and cramps, dermatitis, eczema, rash, peripheral oedema, fluid retention, fatigue, neutropenia, thrombocytopenia or anaemia.

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, oedema (including brain, eye, pericard, abdomen and lung), haemorrhage (including brain, eye, kidney and gastrointestinal tract), diverticulitis, gastrointestinal perforation, tumor haemorrhage/ 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 positive opinion , recommending , will be considered , is expected , can , hopeful news , suggested connection , 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 the European Commission will follow the CHMP recommendation or issue a final decision within the expected time frame or that the US Food and Drug Administration will approve the pending applications for additional

marketing authorizations for Glivec. There can be no guarantee that Glivec will be approved for any additional indications in any market or reach any particular sales levels. Finally, there can be no guarantee regarding the long-term impact of a patient s use of Glivec. In particular, management s expectations regarding commercialization of Glivec could be affected by, among other things, additional analysis of Glivec clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the ability of Novartis 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 Novartis AG 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 97,000 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: July 28, 2006

By: /s/ MALCOLM B. CHEETHAM

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