NOVARTIS AG
Form 6-K
April 10, 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 April 10, 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: ý 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**: ý

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**: ý

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**: ý

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- Investor Relations Release -

Novartis completes submissions in US and Europe for Glivec® as treatment for four rare types of cancer

Research program based on Glivec-sensitive pathways in multiple rare disorders exemplifies future direction of targeted cancer diagnosis and treatment

Regulatory submissions reflect continued commitment to identifying new therapies for patients with rare diseases who have limited treatment options

Basel, April 10, 2006 Novartis announced today that it has submitted applications in the United States and Europe for Glivec® (imatinib)* as treatment for four rare types of cancer. These filings underscore how cancers of different origin and location can share common pathways that respond to the same targeted treatment.

Thanks to the success of targeted therapies like Glivec, these filings speak to the fundamental shift that we are seeing in the approach to cancer treatment, said Diane Young, Vice President and global head of Clinical Development at Novartis Oncology. One day, cancer may no longer be classified by site, or even by single genes or proteins, but instead by the way in which the cancer is expressed. This could potentially give rise to more targeted treatment options such as Glivec.

Glivec targets the activity of proteins called tyrosine kinases that play important roles within some cancer cells. Glivec has been shown to inhibit the function of the tyrosine kinase Bcr-Abl in Philadelphia-chromosome positive (Ph+) chronic myeloid leukemia (CML), and the receptor tyrosine kinase Kit in Kit (CD117)-positive gastrointestinal stromal tumors (GIST). Researchers have found that Glivec also inhibits other receptor tyrosine kinases, including platelet-derived growth factor (PDGFR), that have been shown to be activated in disease pathways that underlie a number of rare hematologic diseases as well as some solid tumors.

The diseases found to have Glivec-sensitive pathways include the solid tumor dermatofibrosarcoma protuberans (DFSP), a type of tumor that begins as a hard lump found in the skin of the chest, abdomen or leg. Three hematologic diseases were also found: certain forms of

myeloproliferative disorders (MPD), diseases in which too many types of certain blood cells are made in the bone marrow; hypereosinophilic syndrome (HES), which is characterized by the persistent overproduction of the white blood cells eosinophils; and systemic mastocytosis (SM), which is marked by the presence of too many mast cells, a certain type of white blood cell. These diseases are rare but may be life threatening. For many of the patients who suffer from them, no approved treatment is available. Novartis submitted the marketing applications in Europe and the United States for DFSP and MPD in 2005 and for SM and HES in 2006.

The submissions are based on a Novartis-sponsored clinical study and clinical data from trials done by independent medical researchers and cooperative trial groups demonstrating efficacy and safety of Glivec in the treatment of these different rare diseases.

* Known as Gleevec® (imatinib mesylate) Tablets in the U.S.

About Glivec

Glivec is indicated in the EU for the treatment of patients with newly diagnosed Ph+ CML for whom bone marrow transplantation is not considered as the first line of treatment. Glivec/Gleevec is approved in the U.S. for newly diagnosed adult patients with Ph+ chronic phase CML and pediatric patients with Ph+ chronic phase CML whose disease has recurred after stem cell (an unspecialized cell that gives rise to differentiated cells) transplant or who are resistant to interferon-alpha treatment. In Japan, Glivec is approved for adult patients in all phases of Ph+ CML. In addition, Glivec is already approved for the treatment of adult patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha treatment in more than 90 countries worldwide.

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. Not all indications are available in every country.

The effectiveness of Glivec is measured by overall hematologic and cytogenetic response rates and progression-free survival in CML and objective response rates in GIST. There are no controlled trials demonstrating increased survival.

Glivec contraindications, warnings and adverse events

The most common undesirable effects experienced during Glivec treatment in GIST are: headache, nausea, vomiting, diarrhea, dyspepsia, myalgia, muscle spasm and cramps, joint swelling, dermatitis, eczema, rash, edema, fluid retention, neutropenia, thrombocytopenia or anemia.

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 continued commitment, one day, may, could potentially, may be 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 commercialization of Glivec could be affected by, among other things, unexpected clinical trial results, including new clinical trial results and additional analysis of existing results; 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 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 91,000 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: April 10, 2006

By: /s/ MALCOLM B. CHEETHAM

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