NOVARTIS AG
Form 6-K
April 16, 2007

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 13, 2007

(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

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- Investor Relations Release -

Positive results prompt US National Cancer Institute to make Glivec® available to patients in post-surgical GIST study

- *Glivec found to dramatically reduce the risk of cancer returning after surgery for Kit-positive gastrointestinal stromal tumors (GIST)*
- *Patients receiving placebo in this trial will now be offered Glivec*
- *Global regulatory submissions planned for use of Glivec as adjuvant therapy in GIST patients following surgery to remove primary tumor*
- *Glivec already approved as effective therapy for patients with advanced metastatic or inoperable Kit-positive GIST*

Basel, April 12, 2007 Investigators will begin offering Glivec® (imatinib)(1) to patients receiving placebo in a major North American clinical trial after after an interim analysis showed participants with Kit-positive gastrointestinal stromal tumors treated with Glivec following surgery were significantly less likely to experience a return of their cancer compared to those not taking this innovative therapy.

The interim analysis showed no recurrence of cancer in approximately 97% of patients given Glivec for a year after surgery to remove tumors, compared to approximately 83% of those who underwent surgery but received a placebo. The investigators made these results public because the study had met its primary endpoint in terms of the rate of recurrence-free survival.

The study involving more than 600 patients was sponsored by the National Cancer Institute (NCI), which is part of the US National Institutes of Health (NIH). It was conducted at multiple cancer centers in the US and Canada, and was led by the American College of Surgeons Oncology Group. Novartis supplied Glivec for use in the study, and also provided partial funding under a Cooperative Research and Development Agreement with NCI to support the clinical development of Glivec.

Glivec has already been confirmed as an effective therapy in its approved use for patients with advanced metastatic or unresectable (inoperable) Kit-positive GIST. In a statement issued today by the NIH, the new findings were heralded as excellent news, with major implications for patients with primary disease.

With these new data, we see that Glivec may help patients with early GIST, said Diane Young, MD, Head of Global Medical Affairs at Novartis Oncology. We will now work with the investigators on a submission to gain regulatory approval for Glivec as adjuvant treatment for GIST.

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

Following the recommendation of a data monitoring committee, the study will be closed and patients in the study who are currently being treated with placebo may choose to receive one year of Glivec.

In the study, patients were randomized to one of two treatment arms. Neither the patients nor physicians knew which treatment the patients were receiving. One patient group received Glivec at a dose of 400 mg per day for one year, while the second group received placebo for one year. According to the study design, patients who developed a recurrence of their cancer while on a study therapy were unblinded to their treatment assignment. Those receiving placebo subsequently received Glivec, while those already given Glivec continued with this therapy but at a higher dose. Study results will be presented at a forthcoming scientific meeting.

Gastrointestinal stromal tumors (GIST) belong to a group of cancers known as soft tissue sarcomas that usually arise from the intestinal tract, with the most common site being the stomach and followed by the small intestine. The incidence of GIST is estimated to be 4,500-6,000 new cases per year in the US (15-20 cases per million population), of which more than 90% are Kit-positive.

Investigators in the NCI study reported that Glivec therapy was well tolerated by most patients, with side effects similar to those observed in other clinical trials with Glivec. These include nausea, diarrhea and swelling (edema). Information on more than 600 patients enrolled in the study was used in the analysis.

About Glivec

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 (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 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 will, planned, or similar expressions, or by express or implied discussions regarding potential future regulatory submissions, new indications or new labeling for Glivec, 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that additional regulatory submissions will be made in any particular jurisdictions, or that Glivec will be approved for any additional indications or labeling in any market. Nor can there be guarantee regarding the long-term impact of a patient s use of Glivec. Neither 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, cure 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. 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. Novartis is the only company with leadership positions in these areas. In 2006, the Group s businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 101,000 associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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5

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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 14, 2007

By: /s/ Malcolm B. Cheetham

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