NOVARTIS AG
Form 6-K
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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 March 18, 2009

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(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:

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Yes: o **No**: x

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- Investor Relations Release -

Glivec® substantially reduces risk of cancer returning in patients with life-threatening gastrointestinal stromal tumors, *The Lancet* reports

- *Estimated one-year, recurrence-free survival was 98% for gastrointestinal stromal tumor (GIST) patients taking Glivec vs. 83% for patients taking placebo(1)*

- *Historically, one in two patients experienced recurrence of GIST(2) within a median of two years after surgery(3)*

- *Glivec is the only treatment in the US and Switzerland indicated to reduce risk of recurrence of GIST after surgery; regulatory review is underway in the EU(4)*

Basel, March 18, 2009 Data published today online and in an upcoming print issue of *The Lancet* show that Glivec®* (imatinib), when taken after surgery, substantially reduces the rate of recurrence of Kit-positive gastrointestinal stromal tumors (GIST) compared with placebo.

The Phase III study published today was led by the American College of Surgeons Oncology Group (ACOSOG) and examined post-surgery, or adjuvant, treatment of more than 700 GIST patients. Researchers found that 98% of patients receiving 400 mg of Glivec daily remained tumor-free one year after surgery. The study also found Glivec to be safe and well-tolerated, with a low rate of serious adverse events(1).

GIST is a life-threatening cancer of the gastrointestinal tract. After initial surgery to remove the tumor, GIST can return in one of two patients(2) within a median of two years(3).

The standard of care after surgical removal of primary GIST has been clinical and radiologic observation, since standard chemotherapeutic agents have been ineffective in this disease. This frequently resulted in tumor recurrence, said Ronald DeMatteo, MD, Memorial Sloan Kettering

Cancer Center, New York, NY. Now, as *The Lancet* reports, by treating patients with Glivec after removal of their initial tumor, we can proactively impact the course of this disease by delaying, and in some patients possibly preventing, the return of the cancer.

Glivec was recently approved in the US, Switzerland and several other countries for the treatment of GIST in the adjuvant setting(4), based on the ACOSOG data. This approval represented the tenth indication for Glivec in the US.

Study details

The double-blind, randomized, multicenter study was conducted throughout the US and Canada. It included 713 GIST patients whose tumors had been surgically removed. The study compared the recurrence-free survival (RFS) of patients taking either Glivec 400 mg daily or placebo immediately following surgery. The results showed that 98% of those receiving Glivec remained recurrence-free one year following surgery compared with approximately 83% of those receiving placebo ($P<0.0001$)(1).

The investigators reported that Glivec therapy was well tolerated by most patients, with side effects similar to those observed in previous clinical trials with Glivec. These include nausea, diarrhea and swelling (edema)(1).

About gastrointestinal stromal tumors (GIST)

Gastrointestinal stromal tumors (GIST) belong to a group of cancers known as soft tissue sarcomas(3). The most common sarcomas, they can be found most often in the stomach and small bowel(3). In the EU, the incidence of GIST is estimated to be more than 5,000 cases per year(5),(6), of which approximately 95% are Kit-positive(3). Median time to recurrence is approximately two years(3). Kit (also known as CD117) is the protein that, when mutated, has been identified as one of the major causes of GIST. Glivec inhibits the activity of several proteins, including Kit(3).

About Glivec

Glivec is approved in more than 90 countries including the US, EU and Japan, for the treatment of all phases of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML). Glivec is also approved in the US, EU 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 the US, Glivec was recently approved for the post-surgery treatment of adult patients following complete surgical removal of Kit (CD117)-positive gastrointestinal stromal tumors. 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 hematological and cytogenetic response rates and progression-free survival in CML, on hematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on hematological response rates in systemic mastocytosis (SM), HES/CEL, on objective response rates and progression-free survival in unresectable and/or metastatic GIST, on recurrence free survival in adjuvant GIST and on objective response rates in DFSP. Increased survival in controlled trials has been demonstrated only in newly diagnosed chronic phase CML and GIST.

Not all indications are available in every country.

Important safety information

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 and 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 and 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 estimated, probably or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Glivec, regarding the long-term impact of a patient s use of Glivec, or regarding potential future revenues from Glivec. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and 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 or labeling in any market. Neither can there be any guarantee regarding the long-term impact of a patient s use of Glivec. Nor can there be any guarantee that Glivec will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Glivec could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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; the impact that the foregoing factors could have on the values attributed to the Novartis Group s assets and liabilities as recorded in the Group s consolidated balance sheet, 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 the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, preventive vaccines, diagnostic tools, cost-saving generic pharmaceuticals and consumer health products. Novartis is the only company with leading positions in these areas. In 2008, the Group s continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 96,700 full-time-equivalent associates and operate in more than 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: March 18, 2009

By: /s/ MALCOLM B. CHEETHAM

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