

NOVARTIS AG  
Form 6-K  
May 08, 2009

## **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 May 7, 2009**

**(Commission File No. 1-15024)**

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**Novartis AG**

**(Name of Registrant)**

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**Switzerland**

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**- Investor Relations Release -**

**Glivec® approved in EU as first post-surgery therapy to reduce risk of cancer returning in patients with aggressive gastrointestinal tumors**

- *Post-surgery use of Glivec shown to reduce the risk of gastrointestinal stromal tumors (GIST) returning by 89%(1)*
- *GIST are a rare, aggressive and potentially deadly type of cancer(2),(3)*

**Basel, May 7, 2009** Glivec® (imatinib)\* received approval from the European Commission (EC) to become the first and only treatment available in Europe to reduce the risk of recurrence in adult patients who are at significant risk of relapse following surgery to remove gastrointestinal stromal tumors (GIST).

A rare, life-threatening cancer of the gastrointestinal tract, GIST are known to be aggressive(2),(3), returning in as many as half of all patients(4) within a median of two years after initial surgery(2). However, data from a pivotal Phase III study recently found that when patients with GIST were treated with post-surgery, or adjuvant, Glivec, the risk of recurrence was reduced by 89%(1).

The EC decision applies in all 27 European Union (EU) member states, plus Norway and Iceland. The approval represents the tenth indication for Glivec in the EU and follows recent approvals for similar indications in the US, Switzerland and several other countries(5).

The approval of Glivec for post-surgery GIST means that for the first time, patients in Europe with this life-threatening disease will have a treatment option that can significantly reduce their risk of GIST coming back after surgery, said Alessandro Riva, MD, Executive Vice President, Global Head, Novartis Oncology Development.

**Study details**

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The EU approval is based on Phase III data from a double-blind, randomized, multicenter study of 713 GIST patients throughout the US and Canada whose tumors had been surgically removed. The study, conducted by the American College of Surgeons Oncology Group (ACOSOG), compared the recurrence-free survival of patients taking either Glivec 400 mg daily or placebo for one year immediately following surgery. The results showed that 98% of the patients receiving Glivec remained recurrence-free after one year compared with approximately 82% of those receiving placebo ( $P < 0.0001$ ). Therefore, the risk of recurrence was reduced by approximately 89% with Glivec as compared to placebo(1).

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

### **About gastrointestinal stromal tumors (GIST)**

GIST belong to a group of cancers known as soft tissue sarcomas(2). The most common sarcomas, they can be found most often in the stomach and small bowel(2). In the EU, the incidence of GIST is estimated to be more than 5,000 cases per year(6),(7), of which approximately 95% are Kit-positive(2). Kit is the protein that, when mutated, has been identified as one of the major causes of GIST. Glivec inhibits the activity of Kit, as well as several other proteins(2).

### **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 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 and EU, Glivec is now 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 and for the treatment of patients with myelodysplastic/myeloproliferative diseases (MDS/MPD). In addition, Glivec is 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 and MDS/MPD; on hematological response rates in systemic mastocytosis (SM) and 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 risk, potentially, will, estimated, 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 clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing 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; 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools 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 98,000 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: May 7, 2009

By: /s/ MALCOLM B. CHEETHAM

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