NOVARTIS AG
Form 6-K
December 23, 2008

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 December 19, 2008

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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- Investor Relations Release -

Glivec receives US approval as first treatment to reduce risk of cancer returning in patients with gastrointestinal stromal tumors

- *Use of Glivec after surgery shows significant benefit for gastrointestinal stromal tumor (GIST) patients, dramatically reducing risk of relapse*

- *GIST, a life-threatening cancer, recurs in as many as one of two patients; recurrent tumors are often more aggressive than primary tumors*

- *For GIST patients who were assigned to Glivec, more than nine out of 10 remained cancer-free based on a 14-month median follow up*

Basel, December 19, 2008 Novartis announced today that Glivec® (imatinib)* has been approved by the US Food and Drug Administration (FDA) for the post-surgery treatment of adult patients following complete surgical removal of Kit (CD117)-positive gastrointestinal stromal tumors (GIST).

Glivec is now the only post-surgery treatment indicated to delay the return of this highly aggressive cancer, filling a major need for GIST patients. The filing received FDA priority review status in August of this year, with regulatory reviews currently underway in other regions, including the European Union and Switzerland.

GIST is a life-threatening cancer of the gastrointestinal tract. After initial removal, GIST tumors can return in as many as one of two patients(1). Recurrent GISTs are often more aggressive than primary tumors, with relapses associated with lower survival rates(2).

After surgery, my doctor told me there was a high likelihood that my gastrointestinal tumors would come back. I immediately searched for a possible solution and found the Glivec clinical trial, which aimed to help patients like me, said Roslyn Fuller, a GIST patient. This FDA approval is good news for me and other GIST patients who will now have the option to start treatment with Glivec earlier to help prevent recurrence.

The approval for this new indication is based on data from a National Cancer Institute-sponsored Phase III study that showed a dramatic reduction in the return of GIST after surgery in patients treated for about one year with Glivec versus placebo. Based on a 14-month median follow up, 91.6% of Glivec patients remained cancer-free compared with 80.2% of those taking placebo(3).

When Glivec was first approved for the treatment of inoperable and/or metastasized Kit-positive GIST six years ago, it revolutionized the treatment of this life-threatening cancer, said David Epstein, President and CEO, Novartis Oncology. This latest FDA approval means patients can benefit from Glivec earlier in the course of their disease.

Glivec is now approved for nine indications, including the treatment of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML), Kit (CD117)-positive gastrointestinal stromal tumors which cannot be surgically removed and/or have already spread to other parts of the body (metastasized) and five other rare diseases.

Filing data

The FDA regulatory filing for the adjuvant GIST indication was based on data from a Phase III, double-blind, randomized, multicenter, international study of more than 700 GIST patients who had undergone surgery to remove their tumors. The efficacy endpoint of the study was recurrence-free survival (RFS), defined as the time from the date of randomization to the date of recurrence or death from any cause. Participants were randomized to receive either Glivec 400 mg/day or a matching placebo for one year(4).

With a median follow-up of 14 months, there were 30 RFS events out of 359 patients in the Glivec arm (8.4%) compared to 70 RFS events out of 354 patients in the placebo arm (19.8%) (hazard ratio=0.398 [95% CI: 0.259, 0.610], p<0.0001). This follow up is too short to evaluate survival(3).

The study, known as ACOSOG Z9001, was conducted at multiple cancer centers throughout the US and Canada under a Cooperative Research and Development Agreement between Novartis and the National Cancer Institute. The study was led by the American College of Surgeons Oncology Group (ACOSOG) in association with the Duke Clinical Research Institute(4).

The investigators reported that Glivec therapy was generally well tolerated by most patients, with side effects similar to those observed in previous clinical trials with Glivec. The most frequently reported adverse reactions were diarrhea, fatigue, nausea, edema, decreased hemoglobin, rash, vomiting and abdominal pain. No new adverse reactions were reported in the adjuvant GIST treatment setting that had not been previously reported in other patient populations including patients with unresectable and/or malignant metastatic GIST(4).

About gastrointestinal stromal tumors

Gastrointestinal stromal tumors (GIST) belong to a group of cancers known as soft tissue sarcomas. The most common sarcomas, they can be found most often in the stomach and 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)(5), of which more than 90% are Kit-positive(6). Kit also known as CD117 is a protein that, when mutated, has been identified as one of the major causes of GIST. Glivec inhibits the activity of several proteins such as Kit.

About Glivec

Glivec is approved in more than 90 countries including the US, EU and Japan for the treatment of all phases of Ph+ 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 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 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 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.

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 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, 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, can, likelihood, aimed to, will, or similar expressions, or by express or implied discussions regarding potential new indications or labelling for 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 labelling in any market. 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group s continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 97,000 full-time associates 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: December 19, 2008

By: /s/ MALCOLM B. CHEETHAM

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