NOVARTIS AG
Form 6-K
December 12, 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 8, 2008

(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: x Form 40-F: ¨

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: ¨ **No: x**

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: ¨ **No: x**

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: ¨ **No: x**

Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

http://www.novartis.com

- Investor Relations Release -

Tasigna® demonstrates rapid response as initial therapy in life-threatening form of leukemia

- *Tasigna now shows potential to become the treatment of choice for certain newly diagnosed patients with chronic myeloid leukemia*

- *Two separate studies show rapid elimination of cancer cells in 96% of Tasigna patients and reduction of abnormal CML protein by six months*

- *Larger front-line Phase III trial evaluating Tasigna vs. Glivec® now fully accrued*

Basel, December 8, 2008 New results from two separate trials demonstrate that Tasigna® (nilotinib) is effective and helps achieve rapid responses when used as initial therapy in newly diagnosed patients with a life threatening form of leukemia. The studies were presented today at the 50th Annual Meeting of the American Society of Hematology.

In both Phase II studies, 96% of patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) achieved a complete cytogenetic response (CCyR) after six months of Tasigna treatment[(1), (2)]. CCyR is defined as undetectable Philadelphia chromosome cells in a patient s bone marrow.

Although CCyR is the primary goal of therapy, achieving major molecular response (MMR) may be the best predictor of long-term progression-free survival. In the two studies, 74%[(2)] and 45%[(1)] of patients treated with Tasigna exhibited MMR after six months. Tasigna was well tolerated in both studies.

Newly diagnosed patients taking Tasigna experienced remarkable responses with minimal toxicity, said Jorge Cortes, MD, Professor of Medicine and Deputy Chair of Leukemia at the University of Texas MD Anderson Cancer Center in Houston. These results indicate there is potential for patients to reach important clinical milestones faster.

Glivec[(1)](imatinib) is the standard treatment for Ph+ CML and rapidly transformed the treatment of CML when it was introduced in 2001. An ongoing Phase III trial called ENESTnd (Evaluating Nilotinib Efficacy in Clinical Trials of Newly Diagnosed Ph+ CML Patients) is evaluating Tasigna vs. Glivec in newly diagnosed patients and is now fully accrued. Data from ENESTnd will be reported once available.

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

Building on the wealth of scientific and clinical knowledge we have gained with Glivec, Novartis strives to continually uncover novel approaches to help Ph+ CML patients achieve the best long-term outcomes, said David Epstein, President and CEO, Novartis Oncology.

Tasigna is a tyrosine kinase inhibitor approved for the treatment of patients who are resistant or intolerant to prior treatment including Glivec. Tasigna is specifically designed to target the Bcr-Abl protein, which is produced only by cells containing the abnormal Philadelphia chromosome, and is recognized as the key cause of the overproduction of cancerous white blood cells. The Philadelphia chromosome is found in nearly all patients with CML.

Study results

The first study, conducted by the Gruppo Italiano Malattie Ematologiche dell Adulto (GIMEMA), is an ongoing, open-label, single-stage, multicenter Phase II clinical trial, designed to evaluate the therapeutic efficacy and safety of Tasigna 800 mg/day as a first-line treatment. Seventy-three patients with newly diagnosed Ph+ CML in early chronic phase are enrolled in the trial. After six months of treatment, 96% of patients had achieved CCyR(2).

In addition, 74% of patients achieved MMR, defined as Bcr-Abl/Abl ratio < 0.1%. The percentage of patients achieving this level of response rapidly increased after one month of treatment. Adverse reactions were manageable with dose adaptations. The incidence of any Grade 2 and 3 non-hematologic adverse events decreased considerably between months one to three and months four to six(2).

The second study, conducted by researchers at MD Anderson Cancer Center, is an ongoing Phase II clinical trial investigating the efficacy and safety of Tasigna as initial therapy for patients with CML-CP (chronic phase). The current analysis, which includes data from 48 patients, shows that nearly all evaluable patients (96%) achieved CCyR. By six and 12 months, 45% and 52% of patients achieved MMR, respectively. Adverse reactions were manageable with temporary treatment interruptions or dose reductions(1). Notably, there was no marked incidence of severe fluid retention or effusions, side effects commonly observed with other drugs of this class.

Tasigna important safety information

Because taking Tasigna with food may increase the amount of drug in the blood, Tasigna should not be taken with food and patients should wait at least two hours after a meal before taking Tasigna. In addition, no food should be consumed for at least one hour after the dose is taken.

Tasigna has been approved in more than 50 countries. In countries where it is approved, Tasigna is indicated for the treatment of chronic phase and accelerated phase Philadelphia chromosome-positive chronic myelogenous leukemia in adult patients resistant or intolerant to at least one prior therapy, including Glivec. The effectiveness of Tasigna is based on confirmed hematologic and unconfirmed cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

The most frequent Grade 3 or 4 adverse events for Tasigna were primarily hematological in nature and included neutropenia and thrombocytopenia. Elevations were seen in bilirubin, liver function tests, lipase enzymes and blood sugar, which were mostly transient and resolved over time. These cases were easily managed and rarely led to discontinuation. Pancreatitis was reported in less than 1% of cases. The most frequent non-hematologic drug-related adverse events were rash, pruritus, nausea, fatigue, headache, constipation and diarrhea. Most of these adverse events were mild to moderate in severity.

Tasigna should be used with caution in patients with uncontrolled or significant cardiac disease (e.g., recent heart attack, congestive heart failure, unstable angina or clinically significant bradycardia), as well as in patients who have or may develop prolongation of QTc. These include patients with abnormally low potassium or magnesium levels, patients with congenital long QT syndrome, patients taking anti-arrhythmic medicines or other drugs that may lead to QT prolongation. Low levels of potassium or magnesium must be corrected prior to Tasigna administration. Close monitoring for an effect on the QTc interval is advisable and a baseline ECG is recommended prior to initiating therapy with Tasigna and as clinically indicated.

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 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.

Not all indications are available in every country.

Glivec 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, fluid retention, as well as neutropenia, thrombocytopenia and anemia. Glivec was generally well-tolerated in all of the studies 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 suggesting, may, commitment, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Tasigna, the long-term impact of a patient s use of Tasigna or regarding potential future revenues from Tasigna. 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 Tasigna to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Tasigna will be approved for any additional indications or labeling in any market. Nor can there be any guarantee regarding the long-term impact of a patient s use of Tasigna. Neither can there be any guarantee that Tasigna will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Tasigna 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.

References

(1) Cortes J, et al. Efficacy of Nilotinib (AMN107) in Patients (Pts) with Newly Diagnosed, Previously Untreated Philadelphia Chromosome (Ph)-Positive Chronic Myelogenous Leukemia in Early Chronic Phase (CML-CP). Abstract # 446. American Society of Hematology 2008 Annual Meeting, San Francisco, CA

(2) Rosti G, et al. High and Early Rates of Cytogenetic and Molecular Response with Nilotinib 800 Mg Daily as First Line Treatment of Ph-Positive Chronic Myeloid Leukemia in Chronic Phase: Results of a Phase 2 Trial of the GIMEMA CML Working Party. Abstract # 181. American Society of Hematology 2008 Annual Meeting, San Francisco, CA.

###

Novartis Media Relations

Central media line : +41 61 324 2200
Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Kim Fox
Novartis Oncology
+1 862 778-7692 (direct)
kim.fox@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone:	+41 61 324 7944
Ruth Metzler-Arnold	+41 61 324 9980
Pierre-Michel Bringer	+41 61 324 1065
John Gilardi	+41 61 324 3018
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

e-mail: investor.relations@novartis.com

North America:	
Richard Jarvis	+1 212 830 2433
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+1 212 830 2456

e-mail: investor.relations@novartis.com

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 8, 2008

By: /s/ MALCOLM B. CHEETHAM

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