

NOVARTIS AG  
Form 6-K  
September 24, 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 September 21, 2007

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

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**Switzerland**

(Address of Principal Executive Offices)

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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

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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:

No:

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**- Investor Relations Release -**

**Tasigna® recommended for European approval to treat rare form of leukemia no longer responding to Glivec®**

*European Union CHMP recommendation based on high response rates and manageable safety profile in patients resistant or intolerant to Glivec*

*Tasigna reduced or eliminated cells carrying a defective chromosome that causes chronic myeloid leukemia in 49% of patients with chronic phase disease*

*Rapid development of Tasigna demonstrates commitment to speeding innovative medicines to patients with unmet medical needs*

**Basel, September 21, 2007** Novartis has received a positive opinion supporting European Union approval of Tasigna® (nilotinib), a selective targeted therapy for patients with chronic myeloid leukemia (CML) who are resistant or intolerant to treatment with Glivec® (imatinib).(1)

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

The Committee for Medicinal Products for Human Use (CHMP) has recommended approval of Tasigna based on positive findings from a pivotal Phase II trial. The European Commission generally follows the recommendations of the CHMP and delivers its final decision within three months. The decision will be applicable to all 27 EU member states plus Iceland and Norway.

Taken twice daily, Tasigna inhibits production of cells containing an abnormal chromosome by targeting the production of the Bcr-Abl protein. This protein, which is produced by cells containing the abnormal Philadelphia chromosome, is recognized as the key driver of the overproduction of cancer-causing white blood cells in patients with CML. Data from the Phase II study show Tasigna reduced or eliminated cells carrying the abnormal chromosome in nearly half of patients (49%) with the chronic phase of the disease.

Tasigna represents a tremendous advance for the small number of patients who develop resistance or intolerance to Glivec, said David Epstein, President and CEO of Novartis Oncology. We are proud to have leveraged our expertise in targeted therapy to deliver a new treatment option only six years after introducing a breakthrough therapy for this form of life-threatening blood cancer.

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Recent landmark clinical trial results for Glivec show that nearly 90% of newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) CML adult patients treated with Glivec were alive after five years(1), but some develop resistance or cannot tolerate this therapy.

Applying key learnings from Glivec, a team of Novartis scientists created Tasigna in August 2002, just a year after the launch of Glivec. Tasigna was specifically designed to preferentially target Bcr-Abl without adding new mechanisms of action that might cause additional side effects. Tasigna moved from synthesis to its first regulatory approval in less than five years.

Tasigna was first approved in Switzerland in July 2007. A regulatory decision in the US is expected by year end and a regulatory submission was completed in Japan during the second quarter. Novartis has launched Phase III studies comparing Tasigna to Glivec in Ph+ CML patients responding sub-optimally to Glivec and in newly diagnosed Ph+ CML patients. A registration study is also underway in certain patients with gastrointestinal stromal tumors (GIST).

The CHMP decision was based on an open-label Phase II study designed to evaluate the safety and efficacy of Tasigna in Glivec-resistant or -intolerant patients with Ph+ CML in chronic and accelerated phase. Efficacy was measured by hematologic response, i.e. normalization of white blood cell counts, and cytogenetic response, i.e. reduction or elimination of the Ph+ chromosome.

Among 320 patients with chronic phase disease, major cytogenetic response (MCyR) was observed in 49% of patients overall, with a MCyR of 47% in patients resistant to Glivec and 52% in intolerant patients. Among 119 patients with accelerated phase disease, major cytogenetic response was observed in 27% of patients and confirmed hematologic response in 42%. Median duration of response had not been reached after a median follow-up of 11.4 months in chronic phase and 6.7 months in accelerated phase patients. Additionally, estimated survival at 12 months was 95.5% in chronic phase and 78.5% in accelerated phase patients.

Chronic myeloid leukemia is one of the four most common types of leukemia, responsible for about 15% of all leukemia cases worldwide(2).

### **Tasigna safety information**

The safety of Tasigna was studied in 438 patients. 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.

The bioavailability of Tasigna is increased by food. Tasigna should not be taken in conjunction with food and should be taken two hours after a meal. No food should be consumed for at least one hour after the dose is taken.

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Studies have also shown virtually no non-hematologic cross-intolerance between Glivec and Tasigna. (Cross-intolerance occurs when patients cannot tolerate two different drugs because of the same side effects). Causes of non-hematologic intolerance to Glivec included Grade 3 or 4 rash/skin toxicity, fluid retention, gastrointestinal intolerance, liver toxicity, and myalgia/arthralgia.

## 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). Glivec has also been approved in various countries for use in treating patients with certain rare types of cancer.

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.

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).

## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as generally follows, should, may, will, expected, or similar expressions, or by express or implied discussions regarding potential regulatory approvals for Tasigna or potential new indications, labeling or future sales of Glivec or Tasigna or regarding the long-term impact of a patient's use of Glivec or Tasigna. 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 or 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 indications in the US, Japan or any other market or that Glivec will be approved for additional indications in any market. Nor can there be any guarantee regarding potential future sales of Glivec or Tasigna or the long-term impact of a patient's use of Glivec or Tasigna. In particular, management's expectations regarding Glivec and Tasigna could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected additional analysis of clinical data, or unexpected new clinical data; competition in general; government, industry, and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; and other risks and factors referred to in Novartis AG's Form 20-F on file with the U.S. 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 more than 100,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

## References

1. Druker, B. et al. Five-Year Follow-up of Patients Receiving Imatinib for Chronic Myeloid Leukemia. N Engl J Med 2006;355:2408-17.
2. Faderl S; Talpaz M; Estrov Z; O'Brien S; Kurzrock R; Kantarjian HM The biology of chronic myeloid leukemia. N Engl J Med 1999 Jul 15;341(3):164-72.

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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: September 21, 2007

By: /s/ MALCOLM B. CHEETHAM  
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Reporting and Accounting