

NOVARTIS AG  
Form 6-K  
July 26, 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 July 25, 2007

(Commission File No. 1-15024)

## Novartis AG

(Name of Registrant)

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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:  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:

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:

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® approved in Switzerland based on impressive efficacy in patients with a form of leukemia no longer responding to Glivec®**

- *First worldwide approval for new anti-cancer therapy designed to more potently and preferentially target the cause of chronic myeloid leukemia*
- *Data show Tasigna to be generally well-tolerated with high response rates and manageable safety profile in patients who are resistant or intolerant to Glivec*
- *US and EU regulatory decisions expected in 2007 with filing in Japan completed during the second quarter*
- *Rapid development of Tasigna demonstrates commitment to speeding innovative medicines to patients with unmet medical need*

**Basel, July 25, 2007** Switzerland has granted the first worldwide approval for Tasigna® (nilotinib), a potent and novel targeted cancer therapy for patients with a form of the life-threatening blood cancer chronic myeloid leukemia (CML) who are resistant or intolerant to treatment with Glivec® (imatinib)(1) the leading therapy for CML patients also developed by Novartis.

The approval of Tasigna came after an accelerated review by the Swiss health authority Swissmedic based on positive findings from a pivotal Phase II trial, Trial results showed high response rates in these patients with a generally well-tolerated, manageable safety profile.

Taken twice-daily, Tasigna inhibits production of cancer cells containing an abnormal chromosome by targeting 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.

In clinical trials, Tasigna reduced or eliminated this abnormal chromosome in 42% of Glivec-resistant patients with Philadelphia chromosome-positive (Ph+) CML in the chronic phase of the disease, as well as in 31% of patients in the accelerated phase of the disease.

While over 90% of patients on Glivec survive after five years, we focused on helping the small percentage of patients who developed resistance or intolerance to Glivec, which led to the discovery of Tasigna, said Dr. Daniel Vasella, Chairman and CEO of Novartis. I am pleased that we set a record of less than five years from synthesis to market, rapidly bringing Tasigna our second-

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

generation, more selective and more potent Bcr-Abl tyrosine kinase inhibitor to those patients who need it.

Additional regulatory decisions on Tasigna are expected in the US and Europe later this year, while a regulatory submission was completed in Japan during the second quarter of 2007. In the US, the Food and Drug Administration requested on July 16 a three-month extension in the regulatory review period.

Also planned for 2007 are Phase III studies involving Tasigna in CML patients responding sub-optimally to other therapies as well as newly-diagnosed CML patients. A registration study is already underway in patients with gastrointestinal stromal tumors (GIST), which can also be treated with Glivec in certain countries.

Recent landmark clinical trial results for Glivec showed that nearly 90% of newly-diagnosed chronic phase Ph+ CML adults patients treated with Glivec were alive after five years<sup>1</sup>, 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 target Bcr-Abl more potently and preferentially 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.

The speed of developing Tasigna reflects our passion to help cancer patients, said David Epstein, President and CEO of Novartis Oncology. A designer cancer treatment, Tasigna also highlights our leadership in targeted therapies.

Chronic myeloid leukemia is one of the four most common types of leukemia, responsible for about 15% of all leukemia cases worldwide<sup>2</sup>, and caused by an overproduction of immature white blood cells. Approximately 95% of CML patients have the Philadelphia chromosome.

#### **Approval based on impressive Phase II results**

Tasigna has been approved for use in the treatment of chronic or accelerated phase of Ph+ CML patients resistant to, or experiencing significant toxicity during treatment with Glivec. The Swiss filing 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 cytogenetic response, i.e. reduction or elimination of the Ph+ chromosome, and hematologic response, i.e. normalization of white blood cell counts..

Among 132 patients with chronic phase disease, major cytogenetic response was observed in 55 patients (42%) after a median of 7.7 months treatment. Among 64 patients with accelerated phase disease, major cytogenetic response was observed after a median of five month follow-up in 20 (31%).

Longer-term data from this pivotal Phase II trial presented last month at the American Society of Clinical Oncology annual meeting showed even further positive results.

#### **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 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, and cumulative high-dose anthracycline therapy. 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.

#### **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 expected, should, planned or similar expressions, or by express or implied discussions regarding potential regulatory approvals for Tasigna or potential 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 Novartis 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 any market, that Tasigna will be brought to market in Switzerland or any additional markets or that Glivec or Tasigna will reach any particular level of sales. There can also be no guarantee regarding 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 additional analysis of clinical data, or 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 discussed in Novartis 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: July 25, 2007

By: /s/ Malcolm B. Cheetham

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

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