

NOVARTIS AG  
Form 6-K  
August 01, 2003

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## 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 for the month of July 2003  
(Commission File No. 1-15024)

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## Novartis AG

(Name of Registrant)

Lichtstrasse 35  
4056 Basel  
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  Form 40-F

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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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ENCLOSURES

1. Swissmedic grants approval for the antihypertensive Diovan® to be used in the treatment of heart failure
2. Glivec® approved in Japan for treatment of life-threatening gastrointestinal cancer
3. Swissmedic approves Leponex® to treat suicidal behaviour in patients with schizophrenia and schizoaffective disorder

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Swissmedic grants approval for the antihypertensive Diovan® to be used in the treatment of heart failure**

*Novartis' antihypertensive agent Diovan®, has now been approved in Switzerland for the treatment of patients with heart failure who are intolerant of angiotensin-converting enzyme inhibitors.*

Basel, 24 July 2003 The decision by the Swiss Agency for Therapeutic Products (Swissmedic) means that Diovan®, an angiotensin II receptor blocker (ARB), can now be used not only for the treatment of hypertension but also for heart failure – a widespread condition. Diovan is approved for use in patients with heart failure who cannot tolerate angiotensin-converting enzyme (ACE) inhibitors. Heart failure, the most rapidly growing cardiovascular disorder in the world, involves a progressive weakening of the cardiac muscle, with a loss of the heart's ability to pump blood effectively to the rest of the body. In Switzerland, about 100 000 patients suffer from heart failure, with around 20 000 new cases diagnosed each year.<sup>1</sup>

**New indication based on convincing results from Val-HeFT study<sup>2</sup>**

The main basis for the extension of the indication was the Val-HeFT study, which involved 5 010 patients with heart failure in 16 countries. The overall results of this placebo-controlled study show that in patients already taking other heart failure treatments prescribed by their physicians, Diovan leads to a reduction in morbidity and slows down the progression of disease associated with heart failure. All-cause mortality was comparable in the group treated with Diovan and the group receiving placebo. In the Val-HeFT study, the best results with Diovan were obtained in patients who were not receiving ACE inhibitors. Among these patients, a relative reduction of 33% was observed for mortality, 44% for combined mortality/morbidity, and 53% for hospitalizations due to heart failure, compared with placebo.<sup>3</sup>

Guidelines issued by the Swiss Society of Cardiology support the use of Diovan to treat patients with heart failure who cannot tolerate ACE inhibitors<sup>1</sup> Although the benefits offered by ACE inhibitors in heart failure are well known, these drugs cannot be given to certain patients on account of poor tolerance or for other reasons (e.g. cough).

Theodor Sproll, CEO of Novartis Pharma Switzerland, commented: "Diovan is already regarded by physicians as a reliable and effective agent for controlling hypertension. Now they can also prescribe Diovan to improve the condition and alleviate the suffering of their patients with heart failure. This important new indication for Diovan is a result of our major clinical development program, which is designed to help patients throughout the course of cardiovascular disease."

**Over 43 000 patients enrolled in ongoing or planned clinical endpoint studies with Diovan**

With Diovan, Novartis is conducting the world's largest clinical endpoint studies involving an ARB, with more than 43 000 patients included in the program. Besides Val-HeFT, trials examining the effects of Diovan beyond the hypertension indication include VALUE (high-risk patients with hypertension)<sup>4</sup>, VALIANT (post-myocardial infarction patients)<sup>5</sup>, and NAVIGATOR (patients with impaired glucose tolerance – also called pre-diabetes – at high risk for cardiovascular events)

Worldwide and in the US, Diovan is the leading antihypertensive in the ARB class. Diovan has already been approved in other countries including the US for the heart failure indication in patients who cannot tolerate ACE inhibitors.

The foregoing release contains forward-looking statements that can be identified by terminology such as "growing", "improve", "alleviate", "designed to help", or similar expressions, or by express or implied discussions regarding potential future sales of Diovan. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Diovan will reach any particular sales level. In particular, management's expectations regarding Diovan could be affected by, among other things, additional analysis of Diovan clinical data; new clinical data; unexpected clinical trial results; 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; increased government pricing pressures; and other risks and factors referred to in the Company'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 AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately USD 2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 200 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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#### References:

- 1) Hess OM et al.: Empfehlungen zur Diagnose und Behandlung der chronischen Herzinsuffizienz. *Schweizerische Ärztezeitung*;2002;83:1233-1242.
- 2) Cohn JN et al.: A randomized trial of the angiotensin receptor blocker valsartan in chronic heart failure. *N Engl J Med* 2001;345:1667-1675.
- 3) Maggioni AP et al.: Effects of Valsartan on Morbidity and Mortality in Patients With Heart Failure Not Receiving Angiotensin-Converting Enzyme Inhibitors. *J Am Coll Cardiol* 2002;40:1414-1421.
- 4) Mann J et al.: The Valsartan Antihypertensive Long-term Use Evaluation (VALUE) trial of cardiovascular events in hypertension. Rationale and design. *Blood Press* 1998;7:176-183.
- 5) Pfeffer MA et al.: Valsartan in Acute Myocardial Infarction Trial (VALIANT): Rationale and design. *Am Heart J* 2000;140:727-34.
- 6) For details see [www.navigatortrial.com](http://www.navigatortrial.com).

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**Investor Relations Release**

**Glivec®, approved in Japan for treatment of life-threatening gastrointestinal cancer**

Basel, Switzerland, 17 July 2003 Novartis announced today that health authorities in Japan have approved Glivec® (imatinib)\* for the treatment of patients with KIT (CD117) positive gastrointestinal stromal tumors (GISTs), a life-threatening cancer. Historically, GISTs have been very difficult to treat due to their resistance to treatment with available chemotherapy and radiation therapy. Previously, surgery was the only treatment option, resulting essentially in palliation of the disease.

The approval from the Ministry of Health, Labor and Welfare came only six months after Novartis filed for the indication. Glivec was originally granted Orphan Drug status for the GIST indication in Japan in October 2002. The approval was based on clinical data from studies conducted in Japan and Western countries, including the member states of the European Union and the United States, where Glivec is already approved for this indication.

"This approval enables Japanese patients with KIT-positive GISTs to benefit from the remarkable results we've seen with Glivec," said David Epstein, President, Novartis Oncology. "The high response rates in these patients have been extremely encouraging and Novartis is pleased that Japanese regulatory authorities acted swiftly to make the drug available to them."

**Clinical Data**

The Japanese study of Glivec was conducted in 74 patients who received once-daily 400 or 600 mg Glivec, respectively, and the overall response rate was 51% at the time of the data cut-off for the submission.

The Japanese data support the findings of a study that was the basis for marketing approval in the EU and US. In this open-label, multinational study conducted in 147 patients with unresectable and/or metastatic malignant GISTs, patients were randomized to receive either 400 mg or 600 mg of Glivec daily. The overall response rate was 38%, based on confirmed partial responses after a median follow-up of approximately seven months.

Updated data from the multinational study, after a median follow-up of 15 months, were presented in May 2002 at the 38<sup>th</sup> annual meeting of the American Society of Clinical Oncology (ASCO). The data showed that more than 60% of patients with GIST achieved a confirmed partial response to Glivec, and an additional 20% attained some degree of tumor shrinkage or stabilization of their disease. The data also revealed that at a median follow-up of 15 months, 73% of patients remained on the study. Results did not differ substantially between the two randomized dose groups used in the study.

**About GIST**

GISTs are the most common sarcoma of the gastrointestinal tract. In the past, GISTs have been difficult to distinguish from other gastrointestinal sarcomas, however, new, more sophisticated diagnostic tools are changing previous incidence estimates. According to a Swedish study presented at this year's ASCO meeting, the incidence of GIST is estimated at 15 per 1 000 000 people annually, more than three times as high as previously suggested.

About Glivec

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Glivec is approved in the European Union, US, and more than 70 other countries for the treatment of patients with Kit (CD 117)-positive unresectable and/or metastatic malignant GISTs.

Glivec is also indicated for the treatment of newly diagnosed adult and pediatric patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in the EU, Switzerland, and a number of other markets. In Japan, Glivec was initially approved for adult patients in all phases of Ph+ CML in November 2001. Glivec is approved in the US for newly diagnosed adult patients with Ph+ chronic phase CML and pediatric patients with Ph+ chronic phase CML whose disease has recurred after stem cell transplant or who are resistant to interferon alpha therapy. In addition, Glivec is already approved in over 80 countries for the treatment of adult patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon alpha therapy.

### Contraindications, Warnings and Adverse Events

The Japanese trials in patients with GIST showed a safety profile consistent with that previously found in trials from other countries. The most common undesirable effects experienced during Glivec treatment in CML and GIST are: headache, nausea, vomiting, diarrhea, dyspepsia, myalgia, muscle spasm and cramps, joint swelling, dermatitis, eczema, rash, edema, fluid retention, neutropenia, thrombocytopenia or anemia. 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.

The foregoing release contains forward-looking statements that can be identified by terminology such as "enables to benefit," "encouraging" or similar expressions, or express or implied discussions regarding potential future sales of Glivec. Such forward-looking statements reflect the current views of the company 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 regarding future sales of Glivec. In particular, management's expectations regarding Glivec could be affected by, among other things, additional analysis of Glivec clinical data; new clinical data; unexpected clinical trial results; 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; increased government pricing pressures; and other risks and factors referred to in the Company'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.

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Additional information on Novartis Oncology and Glivec can be found at [www.novartisoncology.com](http://www.novartisoncology.com) or [www.glivec.com](http://www.glivec.com). Additional media information can be found at [www.novartisoncologyVPO.com](http://www.novartisoncologyVPO.com).

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Swissmedic approves Leponex® to treat suicidal behaviour in patients with schizophrenia and schizoaffective disorder**

*First medication ever approved for this Indication in Europe*

Basel, 10 July 2003 Novartis announced today that the Swiss Agency for Therapeutic Products (Swissmedic) has granted marketing authorisation for Leponex® (clozapine). In addition to the treatment of schizophrenic patients who fail to respond adequately to standard antipsychotic drug therapies, Leponex is now also indicated for long-term reduction of the risk of recurrent suicidal behaviour in patients with schizophrenia or schizoaffective disorder who are judged to be at such risk based on their clinical history and current clinical picture. This action by Swissmedic marks the first time in Europe that any medication has been approved for use in specifically treating the risk of suicidal behaviour.

The approval is based upon data from the International Suicide Prevention Trial (InterSePT ), the first ever study to prospectively evaluate a medication in reducing the risk of suicidal behaviour.<sup>1</sup> The findings from this two-year landmark study led the US Food and Drug Administration (FDA) to approve the drug marketed in the US under the brand name Clozaril® in December 2002 for the treatment of recurrent suicidal behaviour in schizophrenic and schizoaffective patients who are at chronic risk.

"The risk of suicide attempts in people with schizophrenia is appallingly high and use of Leponex in this population could very well help to save many lives each year," said Dr. Herbert Meltzer, Bixler Chair of Psychiatry and Professor of Pharmacology at Vanderbilt University, and lead author of the publication which appeared in the Archives of General Psychiatry earlier this year. "The InterSePT study showed that for every 13 patients treated with clozapine, there was one less serious suicidal event."

"The findings of the InterSePT study represent an important advance for patients with schizophrenia, their relatives and their physicians," commented Thomas Ebeling, Chief Executive Officer, Division Pharma. "We are very pleased that Swissmedic has recognized the potential of treatment with Leponex to reduce the risk of suicidal behaviour for those patients who are most in need and that Switzerland is the first country in Europe to approve this important new indication for Leponex.

**About suicidal behaviour**

Schizophrenia affects up to 24 million people worldwide. Suicide is the leading cause of premature death among patients with schizophrenia and schizoaffective disorder. 40% of patients with these disorders will attempt suicide at least once during their lifetime and 10% will die by suicide. Suicidal behaviour includes symptoms ranging from having persistent suicidal thoughts, to making suicidal plans and attempting suicide.

**About InterSePT**

InterSePT was a multi-center, randomized study initiated in 1998 to compare the efficacy of two antipsychotic compounds, Leponex and olanzapine, in reducing the risk of suicidal behaviour among patients with schizophrenia or schizoaffective disorder. Leponex reduced the risk of suicidal behaviour (suicide attempts and hospitalisations to prevent suicide) by 26% compared to olanzapine. This advantage was not related to the greater use of concomitant psychotropic medication by Leponex-treated patients who actually required fewer such medications.

This release contains certain "forward-looking statements", relating to the Group's business, which can be identified by the use of forward-looking terminology such as "could", "will", or similar expressions, or express or implied discussions regarding potential future sales of existing products or potential new indications for existing products, or by other discussions of strategy, plans or intentions. Such statements reflect the current views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that existing products will reach any particular sales levels or that any new indications will be approved for existing products in any market. In particular, management's expectations could be affected by, among other things, new clinical data; unexpected clinical trial results; 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; and other risks and factors referred to in the Company'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 described herein as anticipated, believed, estimated or expected.

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*References:*

1. Meltzer, HY, *et al.* Clozapine Treatment for Suicidality in Schizophrenia: International Suicide Prevention Trial (InterSePT) *Arch Gen Psychiatry*. 2003; 60:82-91

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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 31, 2003

By: /s/ MALCOLM B. CHEETHAM

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Name: Malcolm B. Cheetham

Title: *Head Group Financial Reporting and Accounting*

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QuickLinks

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