

NOVARTIS AG
Form 6-K
April 01, 2003

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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 for March 2003

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35
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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):

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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:

Enclosures:

1. New survey indicates need for increased awareness and formal diagnosis of Irritable Bowel Syndrome

2. Data prove Glivec® is superior treatment for patients newly diagnosed with chronic myeloid leukemia
3. Data Show Novartis drug Zometa® offers important advance as first bisphosphonate to significantly reduce bone complications common in kidney cancer
4. Novartis signs collaboration agreement with Regeneron for rheumatoid arthritis compounds
5. Lescol® following angioplasty sharply reduces risk of cardiac events in patients with advanced coronary artery disease down to that of patients with early stage disease

2

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Media Release - Communiqué aux Médias - Medienmitteilung

New survey indicates need for increased awareness and formal diagnosis of Irritable Bowel Syndrome

First pan-European survey of 42 000 people to assess the impact of IBS

Basel, 12 March 2003 The Truth in IBS Survey (TIBS), published today in *Alimentary Pharmacology & Therapeutics* (Vol. 17, No 5), indicates that Irritable Bowel Syndrome (IBS) is a prevalent disorder that seriously impacts the quality of life of sufferers. The TIBS survey, supported by Novartis, interviewed nearly 42 000 people from eight European countries and is the first pan-European survey to assess the prevalence, symptoms, and impact of IBS.

According to the survey results, the majority of IBS sufferers experience the distinct symptoms known to be associated with IBS (i.e. abdominal pain, bloating, and constipation). However, only 2.8% of people surveyed exhibiting these symptoms had been previously diagnosed by a doctor. In addition, 78% of IBS sufferers reported that their general state of health affected their lives. Specific aspects of their lifestyles that were negatively impacted by IBS were diet, concentration, long journeys, physical appearance, the ability to eat out, the ability to lead a "normal" life and sexual relationships. In addition, IBS sufferers reported having more interferences with everyday activities, with an average 3.9 days spent in bed, 5.5 sick days off work, 8.4 days seeing a doctor or nurse and 10.2 days when activities had to be cut short per year.

"The survey, the largest of its kind conducted in Europe, reveals the scale and impact of IBS and the need to be more aware of its existence," said lead investigator A. Pali S. Hungin, Dean of Medicine, University of Durham, UK. "IBS is a disorder that can permeate every sphere of patients' lives, from their jobs and work to sex and family relationships, it is relatively common and often debilitating."

About Irritable Bowel Syndrome (IBS)

IBS is characterized by abdominal pain and discomfort, bloating, and altered bowel function (constipation and/or diarrhea). Until recently, the cause of IBS has been poorly understood and under appreciated. However, in recent years, new research has yielded a better understanding of IBS and its causes. People who have abdominal pain and discomfort, bloating and constipation associated with IBS may have altered sensitivity and altered motility of their lower GI tract. This may be due to the way their lower GI tract reacts to changes in 5HT (serotonin), a naturally occurring chemical, in their body that regulates motility and perception of pain and discomfort in the intestinal system.

3

Key Survey Findings

Results from TIBS show that women are more likely (63%) to suffer from IBS than men. The chief symptoms experienced by IBS sufferers were abdominal pain (88%), bloating (80%), trapped wind (66%), tiredness (60%), diarrhea (59%), tightness of clothing (58%), constipation (53%) and heartburn (47%). On average, 69% reported symptoms lasting one hour, twice daily for 7 days a month. Of all sufferers with current symptoms, 69% had taken some form of prescription or non-prescription therapy to treat their IBS. However, only 38% of respondents reported satisfaction with their treatment, a figure strikingly close to the placebo response rate in most studies of functional problems.

To date, much of the prevalence data on IBS have been influenced by the use of varying methodologies and diagnostic criteria. This makes comparison between countries difficult. Specifically, there has been a shortage of information on the impact and prevalence of IBS in European countries. By collecting data using a standardized methodology, the survey also confirmed the applicability of using randomized research techniques to conduct a large-scale clinical survey.

TIBS was conducted with approximately 5 000 people in each country via random digit dial telephone interviews. Interviews were conducted in the United Kingdom, Italy, France, Switzerland, Germany, Spain, Belgium and The Netherlands. Respondents who were identified as having IBS (formally diagnosed or not) were asked to complete a more in-depth interview about the impact of IBS on their lives. Researchers used IBS sufferers' direct responses to determine the prevalence and impact of IBS, in place of referencing specific diagnostic criteria.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of CHF 32.4 billion (USD 20.9 billion) and a net income of CHF 7.3 billion (USD 4.7 billion). The Group invested approximately CHF 4.3 billion (USD 2.8 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 72 900 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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4

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Media Release - Communiqué aux Médias - Medienmitteilung

Data prove Glivec® is superior treatment for patients newly diagnosed with chronic myeloid leukemia

Nearly three-quarters of patients achieve major treatment goal in study comparing Glivec with traditional therapy; Glivec also significantly delays disease progression

Basel, 13 March 2003 Glivec® (imatinib) should be considered the first drug treatment option for patients with newly diagnosed chronic myeloid leukemia (CML), according to data published in the 13 March 2003 issue of the *New England Journal of Medicine (NEJM)*. They confirm that newly diagnosed patients in the chronic phase of CML are substantially more likely to achieve a complete cytogenetic response, a major goal of treatment, when treated first with Glivec than with the traditional combination therapy, interferon and cytosine arabinoside (IFN/Ara-C). In addition, the data show that Glivec significantly delays the progression of the disease to advanced stages. The data represent 18 months of follow-up from the International Randomized Study of Interferon vs. STI571 (IRIS), the first head-to-head study comparing Glivec with IFN/Ara-C.

"As we look at the benefits of Glivec over a longer period of time, the results continue to be very impressive," said Dr. Stephen G. O'Brien, lead investigator, Department of Hematology, University of Newcastle Medical School, United Kingdom. "By all parameters measured in the IRIS study, early use of Glivec yielded superior results compared to interferon/Ara-C. It is still too early to be sure of long-term outcomes in Glivec-treated patients, but from the results we have seen to date, there is reason for optimism."

Study Details

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The study was conducted in 1 106 patients. At the 18-month follow-up after the last patient was recruited, 74% of newly diagnosed patients treated with Glivec, taken orally at 400 mg daily, had achieved a complete cytogenetic response, compared with 8% of those treated with IFN/Ara-C (P<0.001).** A major cytogenetic response was achieved by 85% of patients taking Glivec compared with 22% of patients treated with IFN/Ara-C (P<0.001). A complete cytogenetic response means that no cells containing the Philadelphia chromosome (Ph+), the genetic abnormality that characterizes most cases of CML, are detected; a major cytogenetic response is defined as the detection of less than 35% Ph+ cells remaining. Patients taking Glivec also had an improved overall progression-free survival compared with those taking IFN/Ara-C (at 18 months: 92% vs. 74%, respectively; P<0.001). A decrease in the progression to more advanced stages of disease (accelerated or blast crisis) with Glivec was also achieved.

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In the US: Gleevec(tm) (imatinib mesylate)

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Based on observed response rate. Estimated rates by Kaplan-Meier analysis demonstrated 76% vs. 14% respectively.

5

Only 2% of patients in the Glivec arm crossed over to the IFN/Ara-C arm, whereas 58% of patients in the IFN/Ara-C arm crossed over to the Glivec arm because of tolerability reasons or lack or loss of response to treatment. Another 12% of patients in the Glivec arm withdrew from the study, compared with 32% of patients in the IFN/Ara-C arm. Severe side effects were much more common in the IFN/Ara-C arm, consistent with the high turnover rate due to intolerance.

These 18-month data were originally presented in December 2002 at the plenary session of the annual meeting of the American Society of Hematology (ASH) in Philadelphia, Pennsylvania, USA.

Glivec

Glivec is indicated for first-line treatment of adult patients with Ph+ CML in the EU, US and Japan and a number of other markets. Marketing approval in the EU, Switzerland and other countries includes the treatment of pediatric patients. 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.

Glivec is also approved in the EU, US and more than 45 other countries for the treatment of patients with Kit (CD 117)-positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumors (GISTs).

Contraindications and Adverse Events

In the first-line study (IRIS), the safety profile with Glivec was similar to that of previous Phase II studies in other CML patients. The majority of patients treated with Glivec experienced adverse events at some time. Most events were of mild to moderate grade and treatment was discontinued for adverse events only in 2% of patients in chronic phase, 3% in accelerated phase and 5% in blast crisis. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, as well as neutropenia and thrombocytopenia.

The foregoing release contains forward-looking statements that can be identified by terminology such as "prove," "should be considered," "superior," "significantly," "substantially," "more likely," "optimism," "very impressive," or similar expressions, or by discussions regarding potential new indications for Glivec, or regarding the long-term impact of a patient's use of Glivec. Such forward-looking statements 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 in any market. Neither can there be any guarantee regarding the long-term impact of a patient's use of Glivec. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of 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; 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 or www.glivec.com. Additional media information can be found at www.novartisoncologyvpo.com.

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