

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)

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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:  Form 40-F:

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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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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

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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.

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## 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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### 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.

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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](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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#### - Investor Relations Release -

#### Data Show Novartis drug Zometa® offers important advance as first bisphosphonate to significantly reduce bone complications common in kidney cancer

*Zometa, a bisphosphonate with demonstrated safety and efficacy across a broad range of solid tumors, may also delay progression of bone lesions in renal cell carcinoma; Data presented at European Association of Urology annual congress*

Basel, 14 March 2003 Treatment with Zometa® (zoledronic acid) reduced by 58% the risk of painful and potentially crippling bone complications in patients with renal cell carcinoma, a type of kidney cancer. In addition, treatment with Zometa significantly delayed onset of the first bone complications. The data, presented at the annual congress of the European Association of Urology (EAU) in Madrid today, are long-term results from a retrospective subset analysis of a larger study, that was included in the dossier given marketing approval in Europe and in the US in 2002.

"Bone complications from kidney cancer can be so crippling that they not only can prevent patients with late stage disease from doing routine, daily activities but may also cause them to be bedridden," said Alan Lipton, MD, key investigator and professor, Department of Medicine, Division of Oncology at the Milton S. Hershey Medical Center, Pennsylvania State University, US. "Zometa can reduce and delay the onset of these common complications helping patients maintain as normal a lifestyle as possible for a longer period of time."

Bone complications, or skeletal related events, are a serious problem for advanced stage cancer patients. They result from the metastases (spread) of cancer to the bone, and include bone pain, pathologic fractures, need for radiation or surgery to bone, spinal cord compression and hypercalcemia. Renal cell carcinoma is the most common type of adult kidney cancer, accounting for 90-95% of tumors arising from the kidney. Approximately 35% of patients with metastatic renal cell carcinoma develop bone complications during the course of their disease.

Zometa is a new generation intravenous bisphosphonate. It is the first therapy of its kind to demonstrate efficacy in prevention of bone complications across a broad range of tumor types including renal cell, breast, prostate, and lung cancers, as well as multiple myeloma. Further, Zometa offers patients and clinicians a convenient 4 mg, 15-minute infusion time.

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## Study Details

The data stem from a retrospective subset analysis of a randomized, placebo controlled study designed to evaluate the efficacy and safety of Zometa in patients with bone metastases from renal cell carcinoma, non-small cell lung cancer and other solid tumors. The primary efficacy endpoint was the proportion of patients who experienced a bone complication. Secondary endpoints included time to first bone complication, skeletal morbidity rate, multiple event analysis, and time to progression of bone lesions. Monitoring of these endpoints helps determine the severity of skeletal complications and how quickly bone metastases are progressing. A total of 773 patients were enrolled in the study. Of these patients, 74 had renal cell carcinoma. Participants were randomized to 4 mg Zometa or placebo via 15-minute infusion every three weeks for 21 months.

In the subset of renal cancer patients, the data showed that significantly fewer patients in the group treated with Zometa (41%) experienced a bone complication compared with those in the placebo group (79%;  $P=0.011$ ), and that Zometa significantly delayed the time to first bone complication (median 424 days vs. 72 days for placebo,  $P=0.007$ ). Also in comparison to placebo, Zometa significantly reduced the annual event rate by about 20% ( $P=0.009$ ) and the risk of developing a bone complication by 58% ( $P=0.010$ ). Additionally, Zometa appears to have delayed the progression of disease in the bone, with a median time to progression of bone lesions at 586 days for the Zometa group, compared with 89 days for the placebo group ( $P=0.014$ ).

## About Zometa

Novartis has received marketing authorization for Zometa in more than 60 countries, including the United States and the member states of the European Union, for the prevention of skeletal related events in patients with advanced malignancies involving bone. These malignancies include multiple myeloma, prostate cancer, breast cancer, lung cancer, renal cancer and other solid tumors. Novartis also has received marketing clearance for Zometa in the treatment of hypercalcemia of malignancy (HCM), also known as tumor-induced hypercalcemia (TIH) in more than 80 countries throughout the world. The proven safety and efficacy of this treatment has resulted in more than 300,000 patients worldwide receiving Zometa to date.

## Contraindications and adverse events

In this study, the incidence of renal adverse events was similar between treatment groups. The most common adverse events reported were bone pain (52% Zometa vs. 68% placebo); nausea (52% vs. 37%); fatigue (33% vs. 16%) and pyrexia (fever; 33% vs. 16%). Based on these results, the authors conclude that Zometa is well tolerated and significantly reduces the risk of skeletal complications in renal cell carcinoma patients with bone metastases, and may also delay disease progression in this population.

In clinical trials in patients with bone metastases, Zometa had a safety profile similar to other intravenous bisphosphonates. The most commonly reported adverse events in bone metastases clinical trials, regardless of causality with Zometa, included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anaemia, weakness, cough, dyspnoea and oedema.

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Zometa is contraindicated during pregnancy, in breast-feeding women and in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa. Zometa and other bisphosphonates have been associated with reports of renal insufficiency. Patients should have serum creatinine assessed prior to receiving each dose of Zometa. Due to the risk of clinically significant deterioration in renal function, single doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes. Since safety and pharmacokinetic data are limited in patients with severe renal impairment, Zometa is not recommended in patients with bone metastases with severe renal impairment. In the clinical studies, patients with serum creatinine  $>3.0$  mg/dL were excluded.

The foregoing release contains forward-looking statements that can be identified by terminology such as "offers important advance," "demonstrate," "reduces," "may also delay" or similar expressions, or by discussions regarding potential new indications for Zometa, or regarding the long-term impact of a patient's use of Zometa. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Zometa to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Zometa 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 Zometa. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of

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Zometa could be affected by, among other things, additional analysis of Zometa 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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### - Investor Relations Release -

#### **Novartis signs collaboration agreement with Regeneron for rheumatoid arthritis compounds**

*Partnership with Regeneron for IL-1 Cytokine Trap compound in phase II clinical development*

*Agreement provides Novartis worldwide co-promotion excluding Japan*

Basel, 28 March 2003 Novartis Pharma AG has signed an agreement to license IL-1 Trap compound from Regeneron, a Tarrytown NY based, publicly quoted, biopharmaceutical company developing therapies for rheumatoid arthritis, cancer, allergy and asthma. Under the terms of the agreement, Novartis will purchase \$48 million of newly issued Regeneron common stock. In addition Novartis will pay Regeneron \$27 million upon closing for its development activities. Further payments are contingent on meeting approval and sales milestones.

Thomas Ebeling, Chief Executive Officer of Novartis Pharma AG, says: "Rheumatoid arthritis afflicts millions of people around the world. Although COX-2 inhibitors and classical non-steroidal anti-inflammatory drugs can successfully treat pain and inflammation for most people suffering from this debilitating condition, they have no effect on the underlying process of bone erosion. IL-1 cytokine Trap technology promises to significantly alter arthritis therapy in the future and represents the next step in a long Novartis commitment to patients with rheumatic conditions."

Cytokines are a family of proteins which regulate various biological processes, and the IL-1 protein is particularly involved in triggering inflammatory responses in the body. In rheumatoid arthritis, an unregulated inflammatory process results in damage to joints. The IL-1 Trap protein is designed specifically to bind to IL-1 and prevent inflammation. The novelty of the Regeneron Trap is its combination of two receptor components in one soluble blocker. Once attached to the Trap, the cytokines cannot trigger inflammation and are eventually flushed from the body. IL-1 Trap is currently being tested in a dose-ranging placebo-controlled phase II clinical trial designed to study safety and efficacy in patients with rheumatoid arthritis. Results of the initial treatment period are expected in the third quarter of 2003.

"We are delighted to embark on this collaboration with Novartis," noted Leonard S. Schleifer, M.D., Ph.D., Regeneron's President and Chief Executive Officer. "With their exceptionally strong skills in development, manufacturing, and marketing, they are ideal collaborators with us. We believe that combining the capabilities of our two organizations gives us an opportunity to accelerate development of the IL-1 Trap and increase its commercial potential, dramatically enhancing our ability to create value for our shareholders."

The agreement allows Novartis to co-develop the IL-1 Trap molecule and provides the company with world-wide marketing rights except for Japan. The partners will co-promote globally, and share profits equally in the EU and the US with Novartis manufacturing commercial supplies upon marketing approval. The deal also includes options to broaden the collaboration and develop other Novartis and/or Regeneron pre-clinical/ early development IL-1 antagonists.

*About Rheumatoid Arthritis*

RA is a debilitating chronic inflammatory disease affecting up to 1% of the population in certain regions of the world. RA most commonly manifests as pain, swelling, inflammation, and ultimately degeneration of the joints, especially in the hands, feet, wrists, and ankles. RA is a systemic disease which can affect the entire body so inflammation may sometimes occur in the blood vessels, heart, eyes, and other organs. Women are afflicted more than twice as often as men. RA can be a disabling, crippling disease due to the joint destruction.

*Disclaimer*

This release contains certain implied "forward-looking statements," relating to the Company's business. Such statements include descriptions of the potential benefits of investigational therapies as evidenced by clinical trial results. Those statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements.

There are no guarantees that the aforementioned trials will result in the commercialization of any of these compounds to treat rheumatoid arthritis in any market. Any such commercialization can be affected by, among other things, uncertainties relating to regulatory actions, delays in or government regulation generally, competition in general and other risks and factors referred to in the Company's current Form 20-F on file with the Securities and Exchange Commission of the United States.

*About Novartis*

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For further information about Novartis Pharmaceuticals Corporation please consult [www.pharma.us.novartis.com](http://www.pharma.us.novartis.com). For further information about Novartis AG, please consult [www.novartis.com](http://www.novartis.com).

*About Regeneron*

Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates for the potential treatment of obesity, rheumatoid arthritis, cancer, and asthma and has preclinical programs in other diseases and disorders.



**Media Release - Communiqué aux Médias - Medienmitteilung**

**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**

*New Findings from LIPS presented at ACC*

Basel, Switzerland, 31 March, 2003 Lescol® (fluvastatin sodium) administered immediately following first angioplasty reduces the risk of fatal and non-fatal serious cardiac events in high-risk patients with more than one blocked coronary artery down to that of lower-risk patients with only one blocked artery, according to a new analysis of the Lescol Intervention Prevention Study (LIPS).<sup>1</sup> These findings were presented at ACC 03 the 52<sup>nd</sup> Annual Scientific Session of the American College of Cardiology by researchers from the Erasmus Medical Centre, University Hospital, Rotterdam, The Netherlands.

"What we are seeing is that fluvastatin therapy begun at the time of angioplasty is, in effect, virtually equalizing the long-term outcomes of multi-vessel and single-vessel diseased patients and that clearly supports a new paradigm for treating the post-percutaneous coronary intervention (PCI) population. The data provides compelling evidence to initiate Lescol therapy as a standard follow-up to an angioplasty procedure, in order to reduce the risk of further cardiac complications," said Professor Serruys, MD, PhD, Professor of Interventional Cardiology at Erasmus Medical Centre.

The new data analysis shows that, without Lescol treatment, patients with multiple blocked coronary arteries had an almost 50 percent higher risk (RR, 1.49; 95% CI, 1.13-1.96) of having a major adverse coronary event (MACE) than patients with only one blocked artery. But in patients who received Lescol following angioplasty, no difference was observed between single and multi-vessel diseased patients in terms of future occurrence of MACE, the researchers concluded. In fact, the patients with multiple blocked arteries who received Lescol experienced a 34 percent reduction (p=0.01) versus placebo in their risk of having a major coronary event.<sup>1</sup> The data also indicate that the patients benefited from treatment with Lescol even if they had cholesterol levels within the normal range.

"The new LIPS data suggest that Lescol therapy brings the risk of multi-vessel disease back to that of an earlier stage in the disease process in post-angioplasty patients. The data also shows that Lescol is beneficial regardless of patients' stage of disease," said Michele Bortolini, MD, clinical program leader, Novartis. "We are excited and intrigued by these findings and will be further studying the anti-atherosclerotic effect of Lescol in existing and new trials."

In addition to further analysis from LIPS, data from new Lescol trials will be available throughout the year. The Assessment of Lescol in Renal Transplantation (ALERT) study is the largest intervention trial in renal transplant patients, and the first attempt to modify cardiovascular outcomes in this high-risk patient population. ALERT will provide insights into Lescol and its effects on MACE reduction among 2,100 patients who were followed for a period of five years or more.<sup>2</sup> It is expected that the results of ALERT will be presented at the American Transplant Congress (ATC) in Washington, DC in June, 2003. The Hypertension High Risk Management Trial or HYRIM, will determine whether Lescol therapy prevents the development or retards the progression of carotid artery atherosclerosis and left ventricular hypertrophy in patients with high blood pressure.<sup>3</sup>

**Background on LIPS**

The LIPS study, which involved 1,677 patients in 10 countries, was designed to determine whether treatment with Lescol reduces MACE in post-angioplasty patients. The study showed that Lescol 80 mg (40 mg twice daily) significantly reduced MACE by 22 percent (p=0.013), even in patients with normal cholesterol levels. In certain high-risk patients, the benefits of Lescol were even more profound. For example, patients with diabetes experienced a 47 percent reduction (p=0.041) in the risk of a serious cardiac event compared with placebo.

Based on the LIPS findings, both Lescol and Lescol XL® 80 mg extended release tablets have already been approved in several countries including the United Kingdom for the secondary prevention of cardiovascular events in patients who have undergone angioplasty and other PCI procedures. Applications for this additional indication are pending in the U.S. and in other markets.

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The LIPS data underscored the excellent safety profile of Lescol: there was no significant difference in elevations of serum creatine phosphokinase (CPK) between Lescol patients and placebo patients. Also, in patients taking Lescol, there were no cases of CPK elevations of 10x upper limits of normal (ULN) or greater. Elevated CPK is an indication of muscle breakdown and is a potential side effect of statin therapies.

These safety data match those from a recent analysis involving more than 9,000 patients of all randomised, controlled clinical trials with Lescol/Lescol XL administered as monotherapy, in which the rate of clinically relevant CPK elevations was similar between Lescol and placebo patients. Additional pooled analysis demonstrates no difference in CK elevation with Lescol in combination with a fibrate compared to monotherapy and placebo.<sup>4</sup>

This release contains certain "forward-looking statements", relating to the business of Novartis, which can be identified by the use of forward-looking terminology such as "will", "expected", or similar expressions, or by express or implied statements regarding the potential for additional sales of Lescol as a result of this new information, or by discussions of potential additional indications for Lescol. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantees that the aforementioned data will result in additional sales or additional indications for Lescol in any market. Any such results can be affected by, amongst other things, uncertainties relating to clinical trial results and product development, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20-F filed with the 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.

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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Lemos P, et al. Fluvastatin Prevents Cardiac Events Following Successful Percutaneous Coronary Intervention in Patients with Multivessel Disease: The Lescol Intervention Prevention Study. Poster presented at ACC-03 the 52nd Annual Scientific Session of the American College of Cardiology, March 2003.

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2

Randomized Double Blind Trial of Fluvastatin For Hypercholesterolemia In Renal Transplant Patients. American Transplant Congress Abstract, 2003.

3

Hypertension High Risk Management Trial (HYRIM). Clinical Study Protocol.

4

Bortolini, M, et al. Frequency of Creatine Kinase Elevation During Treatment with Fluvastatin in Combination with Fibrates (bezafibrate, fenofibrate, gemfibrozil), Results of A Pooled Analysis. Am J Card. Jan. 2003.

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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: April 1, 2003

By: /s/ MALCOLM B. CHEETHAM

## Edgar Filing: NOVARTIS AG - Form 6-K

Name: Malcolm B. Cheetham

Title: *Head Group Financial Reporting and Accounting*

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