

NOVARTIS AG  
Form 6-K  
November 04, 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 the month of October 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:

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:

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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.

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### **MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

#### **UK and Australian health authorities endorse use of Glivec® for first-line treatment of chronic myeloid leukemia patients**

Basel, Switzerland, 30 October 2003 Health authorities in the UK and Australia (the National Institute for Clinical Excellence [NICE] and the Minister of Health and Ageing, respectively) each made announcements last week endorsing the use of the Novartis drug Glivec® (imatinib)\* as first-line treatment for patients newly diagnosed with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in all phases of the disease.

Both health authorities issued their announcements on 22 October 2003. In England and Wales, NICE issued guidelines recommending that newly diagnosed adult Ph+ CML patients should have access to Glivec as their first drug treatment option. The Australian Federal Government will subsidise Glivec for the treatment of newly diagnosed Ph+ CML patients (including pediatric patients).

Previously, each country endorsed the use of Glivec only for Ph+ CML patients in the blast crisis, accelerated phase or in chronic phase after failure or intolerance of interferon-alpha therapy (IFN), a traditional treatment for CML.

"We are pleased that the authorities in both the UK and Australia recognize the importance of providing Ph+ CML patients with access to Glivec as early as possible," said David Epstein, President, Novartis Oncology. "Data show that Glivec as initial therapy results in the greatest overall response and benefit to patients when compared to the previous standard treatment."

Worldwide, CML has an incidence of one-to-two cases per 100 000 population per year and is responsible for 15 to 20% of all adult cases of leukemia.

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For people in chronic phase CML currently receiving IFN as first-line treatment in Australia and the UK, the choice of whether to change to Glivec should be based upon the response of the disease to current treatment and by the tolerance of the patient to IFN. This decision should be made after informed discussion between the patient and the responsible clinician.

In Australia, the Minister for Health and Ageing decides which drugs should be reimbursed on the PBS (Pharmaceutical Benefits "reimbursement" Scheme) based on recommendations from the Pharmaceutical Benefits Advisory Committee (PBAC). This follows approval from the Therapeutic Goods Administration (TGA), which ensures the quality, safety and efficacy of drugs, approving them for sale in Australia.

NICE was established on 1 April 1999 as a Special Institute for England and Wales. It is part of the NHS and its role is to promote high clinical standards in the NHS by developing or commissioning guidance on clinical and cost-effectiveness and disseminating guidance to clinicians, patients and commissioners.

### About Glivec

Glivec is one of the first oncology drugs that validate rational drug design based on an understanding of how some cancer cells work. It is a signal transduction inhibitor, which interferes with the pathways that signal the growth of tumor cells. Glivec works by inhibiting an abnormally activated protein (enzyme) that is coded for by the Ph+, the genetic abnormality that characterizes CML in most patients.

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Glivec is indicated for the treatment of newly diagnosed adult and pediatric patients with Ph+ CML in the EU, Switzerland and a number of other markets. 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 IFN therapy. In addition, Glivec is already approved in more than 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, Japan and more than 70 other countries for the treatment of patients with Kit (CD 117)-positive unresectable (inoperable) and/or metastatic malignant 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 most common undesirable effects experienced during Glivec treatment in 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 "recommending", "should have access", "will subsidise", "should be based", "should be made", "should be reimbursed", or similar expressions, or by express or implied discussions regarding potential future revenue from 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 achieve any particular level of revenue. Neither can there be any guarantee regarding revenues from Glivec. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and 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. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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,

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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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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

#### EMEA approves Stalevo for treatment of Parkinson's disease

*First new levodopa treatment in more than a decade enhances benefits of the most effective and widely used PD therapy*

Basel, 23 October 2003 Novartis announced today in conjunction with Orion Pharma that the European Agency for the Evaluation of Medicinal Products (EMA) has approved Stalevo (levodopa, carbidopa and entacapone), the first new combination including levodopa in more than a decade, for patients with Parkinson's disease (PD) who experience end-of-dose motor fluctuations.

Stalevo contains levodopa, the most effective and widely used agent for Parkinson's disease, plus carbidopa and entacapone. Entacapone and carbidopa are enzyme-blocking compounds that enhance the therapeutic benefits of levodopa by stopping its breakdown within the body.

When a patient first starts taking levodopa treatment, the effect of levodopa lasts for many hours. However within two years, approximately 40% of PD patients receiving levodopa therapy begin to notice that the benefits from their traditional levodopa therapy last for shorter periods of time, a phenomenon known as end-of-dose "wearing-off" or end-of-dose motor fluctuations. Motor fluctuations worsen over time and almost all PD patients go on to develop this treatment complication in the longer term.

"With Stalevo we can enhance the benefits of levodopa and more effectively treat the problems such as "wearing-off" that complicate the long-term use of levodopa and limit its utility. Stalevo thus represent an important advance in our ability to treat Parkinson's disease patients", says Professor David Brooks of the Medical Research Council Clinical Sciences Centre and Imperial College London, UK, one of the lead investigators for Stalevo.

The effectiveness of the combination of levodopa, carbidopa and entacapone in Stalevo in the treatment of Parkinson's disease has been established in multicenter, randomised, double blind placebo-controlled trials in patients experiencing "wearing off". In these trials, therapy with Stalevo was shown to increase "on" time and improve motor function and activities of daily living such as patients' ability to walk, dress, and maintain hygiene. In a separate study, most patients regarded Stalevo as easy to dose, use, handle and swallow.

"Stalevo will provide patients with Parkinson's disease with a new effective treatment to improve their quality of life," said Jörg Reinhardt, Head of Development, Novartis Pharma AG. "Bringing Stalevo to market reinforces our commitment to addressing unmet medical needs and to supporting patients and families affected by disorders such as Parkinson's."

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Stalevo will be available in Europe from Novartis and Orion Pharma, the originator of Stalevo. Stalevo has been available in the USA since mid-August, 2003.

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### About Parkinson's disease

Parkinson's disease, a chronic and progressive neurological condition, affects more than 1% of people over 65 years old. While its cause is unknown, the symptoms of Parkinson's disease result from a destruction of dopamine-containing nerve cells, or neurons, in the *substantia nigra*, a part of the brain that controls movement. Symptoms of Parkinson's disease include limbs that tremble when relaxed; slowness of movement; stiffness and rigidity of limbs and gait or balance problems. As the disease progresses, these symptoms usually increase and impact a person's ability to work and carry out activities of daily living.

This release contains certain forward-looking statements that can be identified by the use of forward-looking terminology such as "will provide", "will be available" or similar expressions, or by express or implied discussions regarding potential future sales of Stalevo. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Stalevo to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee of future sales. In particular, management's expectations regarding Stalevo could be affected by, among other things, unexpected regulatory delays, further clinical trial results regarding efficacy or safety of Stalevo, government regulation or competition in general, increased government pricing pressures, 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. The Company 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 has been a leader in the neuroscience area for more than 50 years, having pioneered early breakthrough treatments for Alzheimer's disease, Parkinson's disease, attention deficit/hyperactivity disorder, Epilepsy, Schizophrenia and migraine, many of which continue to be regarded as "gold standards" to this day. Novartis Neuroscience continues to be at the forefront of research and development of new compounds, is committed to addressing unmet medical needs and to supporting patients and families affected by these disorders.

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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#### Investor Relations Release

FDA issues "approvable" letter for Certican® for heart and kidney transplantation in the US

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Basel 21 October 2003 Novartis Pharma AG announced today that it has received an "approvable" letter from the US Food and Drug Administration (FDA) for Certican® (everolimus), a proliferation signal inhibitor, in combination with cyclosporine for the prevention of rejection episodes following heart or kidney transplantation. Final approval is contingent on Novartis' submission and FDA review of additional clinical data.

"Preventing chronic graft dysfunction is the biggest challenge in transplantation today," said Tony Rosenberg, Head, Transplant and Immunology Business Unit, Novartis Pharma AG. "Certican's ability to reduce the incidence of rejection could offer transplant patients and physicians a powerful new tool. It is expected to be a welcome addition to our established portfolio of marketed products that have enhanced the lives of transplant recipients."

Certican received its first approval from the Swedish Medical Products Agency in July 2003 for the prevention of rejection in heart and kidney transplant patients in combination with Neoral® (cyclosporine for microemulsion). Sweden is the Reference Member State for the Mutual Recognition Process that is currently underway for Certican within the European Union. In Canada, Certican has received a fast-track designation for use in heart transplant patients and is under review for use in kidney transplant patients.

The Novartis Transplantation and Immunology Business Unit is committed to developing an innovative range of therapeutic products for the prevention of organ rejection in order to provide an extensive choice of drugs to the transplant community and to maintain Novartis' role as a global market leader in this field of medicine.

This release contains certain "forward-looking statements," relating to the Company's business, which can be identified by the use of forward-looking terminology such as "approvable", "final approval", "is contingent on", "is expected", "currently underway", "is being reviewed", "is committed" or similar expressions, or by express or implied discussions regarding the approval or marketing of Certican. Such 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 to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There can be no guarantees that Certican will be commercialised in any market. Any such commercialisation can be affected by, among other things, uncertainties relating to the product development and clinical trials, 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 materialise, 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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### NOTES TO EDITORS

Patients receiving organ transplants depend on immunosuppressive drugs to stop their immune systems from attacking and rejecting the transplanted organ (graft). The drug Neoral (cyclosporine for microemulsion) is one of the mainstays of immunosuppression in transplant patients, permitting long-term survival, but the risk of acute and chronic graft rejection persists.

For further information, please access <http://www.transplantsquare.com>

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**Investor Relations Release**

**Visudyne® approved in Japan for treatment of Age-Related Macular Degeneration (AMD)**

Basel, Switzerland and Vancouver, Canada, 16 October 2003 Novartis Pharma AG, Ophthalmics, the eye health unit of Novartis AG and QLT Inc., announced today that health authorities in Japan have approved Visudyne® (verteporfin) for the treatment of the "wet" form of Age-Related Macular Degeneration (AMD), the leading cause of blindness in people over age 50.

Specifically, Visudyne has been approved for the orphan indication of age-related macular degeneration with all types of subfoveal choroidal neovascularisation (CNV). Patients with this serious condition lose their ability to read, drive and recognise faces in a few months.

"We are thrilled that Visudyne has been approved in Japan," said Flemming Ornskov, MD, MPH, Head, Ophthalmics Business Unit, Novartis. "This is another milestone in our continued efforts to bring Visudyne, the standard of care in AMD treatment, to patients worldwide."

Approval was based on the results of a 12-month clinical study conducted in Japan, which confirmed the efficacy and safety profile of Visudyne as demonstrated in 3 large randomised controlled trials conducted in the rest of the world. In fact approximately 3 patients out of 4 participating in this study either maintained or improved their vision as a result of Visudyne therapy.

The submission of a new drug application in Japan for Visudyne was made in April 2002. Visudyne was evaluated in Japan as a therapeutic drug for the wet form of AMD following its designation as an orphan drug in June 1997.

"The approval in Japan is a significant step in our efforts to expand the Visudyne franchise," said Paul Hastings, president and chief executive officer of QLT. "We will now focus our efforts on securing reimbursement to ensure that this treatment is available to the thousands of AMD patients in Japan who previously had no other option due to the lack of any effective means to treat this disease."

Visudyne therapy is a two-step procedure. Following intravenous administration, Visudyne is activated by a non-thermal laser light. The process is known as photodynamic therapy. Visudyne selectively targets abnormal blood vessels under the retina, resulting in a reduction in their growth, without affecting normal/healthy retina tissue. This, in turn, stops the leakage associated with wet AMD. However, it is important for patients to be diagnosed and treated early if they are to gain maximal benefit from treatment with Visudyne. In Japan, Carl Zeiss Co., Ltd., and Lumenis Japan, Ltd. have submitted approval applications for laser devices, which would be used in Visudyne therapy.

**About AMD**

AMD is the leading cause of legal blindness in people over the age of 50. Its associated vision loss has been shown to significantly decrease quality of life. Everyday tasks such as driving and walking can be severely affected. Awareness of the condition is essential for patients to take the necessary steps that lead to diagnosis and early treatment to halt progression of AMD.

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Vision loss from AMD occurs in two forms: dry and wet. The dry form is associated with atrophic cell death of the central retina. The wet form is caused by growth of abnormal blood vessels (CNV) under the central part of the retina or macula. These vessels leak fluid and blood and cause scar tissue that destroys the central retina. This results in a deterioration of sight over a period of months to years.

**About Visudyne**

Visudyne is the only drug approved for the treatment of some forms of wet AMD, and has been used in more than 250,000 patients worldwide. Visudyne is commercially available in more than 70 countries for the treatment of predominantly classic subfoveal CNV and in over 40 countries for occult subfoveal CNV caused by AMD. It is also approved in more than 55 countries, including the EU, US and Canada, for the treatment of subfoveal CNV due to pathologic myopia (severe near-sightedness). In some countries Visudyne is also approved for presumed

ocular histoplasmosis or other macular diseases.

Visudyne is generally well tolerated and has an excellent safety profile. Potential side effects include injection site reactions, back pain, blurring, decreased sharpness and gaps in vision, and in one to five per cent of patients, a substantial decrease in vision with partial recovery. After treatment, patients should avoid direct sunlight for five days to avoid sunburn. People with porphyria should not be treated. For more information visit [www.visudyne.com](http://www.visudyne.com).

*Visudyne® is a trademark of Novartis AG.*

The foregoing press release contains forward-looking statements that can be identified by terminology such as "continued efforts", or by express or implied discussions regarding future plans for Visudyne, or potential future approvals or revenue from the product. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results and assumptions to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Novartis' plans for Visudyne will come to fruition; that Visudyne will be approved for any additional indications in any countries; or that Visudyne will achieve any particular level of revenue. Management's expectations regarding Visudyne may be affected by: risks associated with the development and commercialisation of the treatment, including uncertainties relating to manufacturing, clinical trials, registration, pricing and reimbursement; patient and physician demand for the treatment; competition; any uncertainty regarding patents and proprietary rights; outcome of litigation claims, product liability claims and insurance; government regulation and pricing pressures; anti-takeover provisions; dependence on corporate relationships; volatility of share prices; and additional information and other factors as described in detail in Novartis AG's Form 20-F, and other filings with the US Securities and Exchange Commission.

**Novartis Pharma AG, Ophthalmics:** With worldwide headquarters in Basel, Switzerland, the Novartis Ophthalmics Business Unit is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of Age-Related Macular Degeneration, eye inflammation, glaucoma, ocular allergies and other diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. The North American headquarters is based in East Hanover, New Jersey. Novartis Ophthalmics products are made in Switzerland, France and Canada. For more information, visit [www.novartisophthalmics.com](http://www.novartisophthalmics.com) or [www.novartisophthalmics.com/us](http://www.novartisophthalmics.com/us).

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**QLT Inc.** (Nasdaq:QLTI; TSE: QLT) is a global pharmaceutical company specialising in the discovery, development and commercialisation of innovative therapies to treat cancer, eye diseases and niche areas for which treatments can be marketed by a specialty sales force. Combining expertise in ophthalmology, oncology and photodynamic therapy, QLT has commercialised two products to date, including Visudyne therapy, which is the most successfully launched ophthalmology product ever. For more information, visit our web site at [www.qltinc.com](http://www.qltinc.com)

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Darifenacin increases "warning time" for OAB sufferers**

*Increased "warning time" may allow overactive bladder sufferers to avoid incontinence episodes*

Basel, 10 October 2003 Darifenacin, a new oral treatment for overactive bladder (OAB), has the potential to prolong "warning time" the period between the first sensation of urgency and urination in patients experiencing OAB syndrome. This is according to data presented at the



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International Continence Society's 33<sup>rd</sup> Annual Congress in Florence, Italy<sup>1</sup>. Darifenacin is a new treatment option and the first M<sub>3</sub> selective receptor antagonist (M<sub>3</sub> SRA) currently awaiting regulatory approval in the US and Europe.

As presented by Linda Cardozo, Professor of Urogynaecology at Kings College Hospital London, urgency was reported as being one of the most distressing symptoms for patients with overactive bladder syndrome. It was suggested that, as a result, people who suffer symptoms of an overactive bladder often have a very limited social and personal life with increased psychological problems. Any help in prolonging the warning time between urgency and the embarrassment of incontinence helps the sufferer to lead a more normal life.

The multicentre, randomized, double-blind, placebo controlled study, evaluated the change in warning time of 72 patients either receiving darifenacin 30mg daily or placebo. After two weeks of treatment, patients using darifenacin showed a significant improvement in median warning time of 4.3 minutes compared with patients in the placebo group. This change represented a 22.5% increase in mean warning time for patients taking darifenacin<sup>1</sup>.

Overactive bladder is a very common condition, estimated to affect 16.5% of the worldwide adult population. Symptoms of OAB affect both sexes and increase with age as many as 30 to 50% of women over the age of 50 are estimated to suffer from the symptoms. In many patients, a specific cause cannot be identified. Many do not seek medical help (50-75%) and of those, who have sought medical help, 80% do not receive treatment.

This release contains certain forward-looking statements that can be identified by the use of forward-looking terminology, such as "may", "potential", "suggested", or similar expressions, or by express or implied discussions regarding the potential that Darifenacin will be approved for marketing or regarding potential revenues from Darifenacin. 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 the actual results with Darifenacin to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that Darifenacin will be approved for sale in any market, or regarding potential revenues from Darifenacin. Any such commercialization can be affected by, amongst other things, uncertainties relating to product development, including the results of clinical trials, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection, competition in general, increased government pricing pressures, as well as factors discussed in the Company's Form 20-F filed 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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### Refs:

1. "Can Medication Prolong Warning Time?" Cardozo L, Prescott K, Serdarevic D, Skillern L, poster presented at the International Continence Society, 33<sup>rd</sup> Annual Meeting, Florence, Italy, 5-9<sup>th</sup> October 2003

### Notes to editors

Regulatory applications for Enablex/Emselex (darifenacin hydrobromide) have been submitted to the US and European authorities for the once daily treatment of overactive bladder in doses of 7.5mg and 15mg. On 3 October 2003, the company received an approvable letter from the US Food and Drug administration. Novartis expects to launch Enablex/Emselex globally in 2004.

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### Investor Relations Release

#### **Compelling disease-free survival results in breast cancer trial prompt independent researchers to offer patients the opportunity to switch to Femara®, as reported in New England Journal of Medicine**

*Interim results from first study to explore post-tamoxifen use of Femara® (letrozole) in postmenopausal women with early breast cancer showed dramatically reduced risk of recurrence (43%) and significantly improved disease-free survival*

Basel, Switzerland, 9 October 2003 Postmenopausal women with early breast cancer who completed five years of post-surgical hormonal therapy with tamoxifen benefited significantly from extended adjuvant treatment with Femara® (letrozole), according to interim results of a study published for early online release in today's *New England Journal of Medicine*. The data prompted an Independent Data Monitoring Committee to unblind the study so that patients in the control arm could consider switching from placebo to Femara, according to an announcement at a press conference held today in Toronto, Canada. This international study was coordinated by the National Cancer Institute of Canada Clinical Trials Group, Kingston, Ontario.

"Historically, there has been no proven post-tamoxifen therapy to address the significant ongoing risk of recurrent breast cancer," said Paul Goss, MD, director of Breast Cancer Prevention and Research, Princess Margaret Hospital, Toronto, Canada. "The data announced today provide the first clinical evidence that extended adjuvant drug therapy with Femara, following five years of treatment with tamoxifen, may have a substantial impact on the overall treatment outcome for postmenopausal breast cancer patients." Dr. Goss conceived of, and was international chair of, the clinical trial.

#### **Study Highlights**

The international breast cancer trial of nearly 5 200 women, called MA-17, is the first study to examine the effectiveness of an aromatase inhibitor, Femara, in the extended adjuvant setting, the period following five years post-surgery tamoxifen treatment. During this period, women do not typically receive drug therapy, despite the ongoing risk of breast cancer recurrence.

At a median follow-up of 2.4 years, the data in the Femara group showed a 43% reduction in risk of overall recurrence compared with placebo (P=0.00008) as well as a significant reduction (46%) in spreading contralateral disease, cancer occurring in the other breast. The estimated absolute improvement in disease-free survival at four years was 6% for postmenopausal patients taking Femara compared with placebo (93% Femara vs. 87% placebo). Disease-free survival is defined as the time from randomization to the time of first recurrence of the primary disease in the breast (including contralateral breast), chest wall, nodal or metastatic sites.

According to data from the Early Breast Cancer Trialists' Group, Oxford, UK, more than 50% of breast cancer recurrence happens in women later than five years after initial diagnosis. Tamoxifen, which reduces the risk of breast cancer recurrence during the first five years of post-surgical therapy, has been shown not to be beneficial beyond five years of treatment. Approximately one million

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postmenopausal women worldwide currently receive tamoxifen therapy for reduction of breast cancer recurrence. Tamoxifen is currently considered the gold standard hormonal therapy during the first five years of treatment in this population.

"With this trial, significant progress is being made towards addressing a critical challenge faced by post-menopausal women who have completed early adjuvant treatment for breast cancer the need to protect against the ongoing risk of recurrence following tamoxifen therapy," said Diane Young, MD, vice president, global head, Clinical Development, Novartis Oncology. "Femara has continuously demonstrated remarkable results, and we look forward to data from our ongoing clinical program."

#### **Study Details**

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The MA-17 study is a Phase III, global, double-blind, randomized, multi-center trial. The primary objective of the study is to compare the disease-free survival of postmenopausal women taking Femara vs. placebo after approximately five years of tamoxifen therapy. Ninety-eight percent of the participants have known receptor positive tumors. The remaining patients have tumors that are estrogen receptor unknown. Women were randomized to the two arms of the study and, prior to the change in protocol, were to have received five years' daily treatment with either 2.5 mg of Femara or placebo (oral). Those who switch from placebo to the Femara arm of the study will be now eligible to receive treatment with Femara.

Secondary objectives of the MA-17 study include comparison of overall survival, incidence of contralateral breast cancer, long-term safety of Femara and quality of life. In addition, subsets of the study are exploring the effect of Femara on lipid metabolism and bone mineral density. According to the interim analysis, no difference in cholesterol levels has, so far, been seen between study arms, nor have there been any differences in patient-reported cardiovascular events to date.

### **Additional Femara Adjuvant Clinical Trial**

A second Phase III adjuvant study with Femara is being conducted by the Breast International Group (BIG 1-98) in collaboration with Novartis. This study has four treatment arms comparing five years of Femara, five years of tamoxifen, two years of Femara followed by three of tamoxifen, and two years of tamoxifen followed by three years of Femara. Recruitment in the BIG 1-98 trial was recently closed, with more than 8 000 women enrolled.

### **About Femara**

Femara, an aromatase inhibitor, is an oral once-a-day first-line treatment for postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. It is also approved for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy, and as neo-adjuvant (pre-operative) therapy. Femara is currently available in more than 75 countries worldwide. Not all indications are available in every country.

### **Femara Contraindications and Adverse Events**

In the MA-17 analysis, the most common adverse events were hot flashes, sweating, edema, hypercholesterolemia, headache, arthralgia, myalgia, fatigue, constipation and dizziness, in greater than 10% of patients in either arm of the study. Of these, hot flashes, arthralgia, and myalgia were more common in those receiving Femara than placebo ( $P < 0.05$ ). Vaginal bleeding was more common in those taking placebo ( $P < 0.05$ ).

The number of women reporting a new bone fracture to date is 77/2166 (3.6%) in the Femara group, compared with 63/2157 (2.9%) in the placebo group ( $P = 0.24$ ). The authors noted a trend to more newly diagnosed osteoporosis in women taking Femara (124/2166 [5.7%]) vs. placebo (97/2157 [4.5%]) ( $P = 0.07$ ).

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Femara is contraindicated in patients with known hypersensitivity to Femara or any of its excipients. Femara is generally well tolerated. In a first-line registration trial versus the antiestrogen tamoxifen, the most commonly reported adverse events for Femara were bone pain (22% vs. 21%), hot flushes (19% vs. 16%), back pain (18% vs. 19%), nausea (17% vs. 17%), dyspnea or labored breathing (18% vs. 17%), arthralgia (16% vs. 15%), fatigue (13% vs. 13%), coughing (13% vs. 13%), constipation (10% vs. 11%), chest pain (6% vs. 6%) and headache (8% vs. 6%). Femara may cause fetal harm when administered to pregnant women. There is no clinical experience to date on the use of Femara in combination with other anticancer agents. The incidence of peripheral thromboembolic events, cardiovascular events, and cerebrovascular events was 3-4% in each treatment arm.

The foregoing release contains forward-looking statements that can be identified by terminology such as "offer...opportunity", "could consider," "may have a substantial impact," "look forward," or similar expressions, or by express or implied discussions regarding potential future sales of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There are no guarantees that the aforementioned clinical trial will result in Femara reaching any particular sales levels. In particular, management's expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara 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.

## About Novartis

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>.

For more information on the results of this clinical trial, please visit the Canadian Cancer Society website at [www.cancer.ca](http://www.cancer.ca), or contact the Canadian Cancer Society's information service toll-free in Canada at 1 888 939-3333.

Background material and pictures can be found at:

[http://novartis.imagedirector.net/album?album\\_code=ud0xqs3vki5](http://novartis.imagedirector.net/album?album_code=ud0xqs3vki5)

Additional media information can be found at [www.novartisoncologyvpo.com](http://www.novartisoncologyvpo.com).

Patients and physicians interested in more information regarding Femara or Novartis Oncology can contact the websites [www.novartis.com](http://www.novartis.com), [www.femara.com](http://www.femara.com), or [www.novartisoncology.com](http://www.novartisoncology.com).

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## MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG

### **New study finds Glivec® demonstrated substantially greater molecular response than traditional treatment**

*Molecular response is possible new benchmark for evaluating success of chronic myeloid leukemia treatment, suggest authors of study in New England Journal of Medicine*

Basel, Switzerland, 9 October 2003 Monitoring response at a molecular level may provide a new benchmark in the management of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) and may ultimately play a role in optimizing treatment, suggest authors of a study published today in the *New England Journal of Medicine (NEJM)*. The study demonstrated that Glivec® (imatinib)\* produced a substantially greater molecular response than a traditional combination therapy in patients with newly diagnosed Ph+ CML in the chronic phase.

In CML, a molecular response is the disappearance or reduction in quantities of Bcr-Abl transcripts, which produce the abnormal protein responsible for driving the proliferation of white blood cells that occurs in CML patients. The authors propose that a thousand-fold ( $\geq 3$  log) reduction in levels of Bcr-Abl should be defined as a "major molecular response." They suggest that monitoring the level of Bcr-Abl could prove to be a surrogate for predicting long-term patient outcomes. Based on the data, the authors estimate that 100% of CML patients who have achieved a complete cytogenetic response and who achieve a major molecular response at 12 months would remain progression-free after another year.

"Our findings suggest that in CML, the levels of Bcr-Abl transcripts in the blood correlate with progression-free survival and that molecular response may be an important tool in evaluating the success of treatment," said Dr. Timothy P. Hughes, Division of Hematology, Institute of Medical and Veterinary Science, Adelaide, Australia.

## Study Details

The data come from the International Randomized Study of Interferon vs. STI571 (IRIS), the first head-to-head study comparing Glivec with the traditional combination therapy interferon and cytosine arabinoside (IFN/Ara-C). It enrolled 1,106 patients newly diagnosed with Ph+ CML in the chronic phase.

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The analysis in today's issue of NEJM was based on IRIS data from 12 months of treatment. These data showed that 68% of Glivec-treated patients vs. 7% of IFN/Ara-C-treated patients had achieved a complete cytogenetic response (CCR), which means that at that time point no cells containing the Philadelphia chromosome, the genetic abnormality that characterizes most cases of CML, were detected. CCR is currently used by researchers as a standard tool for gauging the effectiveness of CML treatment.

Updated data from the IRIS study were published in the 13 March issue of NEJM. These data, from the 18-month follow-up after the last patient was recruited, demonstrated that 74% of newly diagnosed patients treated with Glivec, taken orally at 400 mg daily, had achieved a CCR, compared with 8% of those treated with IFN/Ara-C (P<0.001).

To determine molecular response rates, Bcr-Abl transcript levels were measured in a subset of the patients who had achieved CCR, after 12 months of treatment. The investigators used quantitative real-time polymerase chain reaction (Q-PCR), the most sensitive method for monitoring minimal

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residual disease in CML. The results showed that Bcr-Abl levels had fallen >3 log in 57% of patients who had achieved CCR on Glivec, compared with 24% of those patients who had achieved CCR on IFN/Ara-C (p=0.0026). By applying these results to the entire study population, the investigators estimated that a >3 log reduction in Bcr-Abl levels was achieved in 39% of all Glivec-treated patients vs. 2% of all IFN/Ara-C-treated patients at 12 months (p<0.001).

The investigators also conducted a landmark analysis of progression-free survival using patients who were still on treatment at 12 months. For CCR patients with a greater than 3-log reduction at 12 months, the probability of remaining progression-free at 24 months was 100% compared to 95% for CCR patients with a less than 3-log reduction and 85% in patients not in CCR (p<0.001).

Previous studies already have found a correlation between CCR and survival but these data show that patients who achieved a CCR can be further classified into prognostic groups through evaluation of molecular response data by PCR.

### About Glivec

Glivec is indicated for the treatment of newly diagnosed adult and pediatric patients with Ph+ CML in the EU, Switzerland, and a number of other markets. 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 more than 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, Japan and more than 70 other countries for the treatment of patients with Kit (CD 117)-positive unresectable (inoperable) and/or metastatic malignant 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 most common undesirable effects experienced during Glivec treatment in 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 "possible new benchmark," "suggest," "may," "propose," "could prove," "estimate," "would remain," "may be," or similar expressions, or by express or implied discussions regarding potential future revenue from 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 achieve any particular revenue levels in the future. 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

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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

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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

#### Novartis partners with Sankyo on gastro-intestinal drug development program

*Lead drug candidate CS-526 entering clinical trials for potential treatment of gastro-esophageal reflux disease (GERD) and peptic ulcers*

Basel, 8 October 2003 Novartis has signed an agreement with Sankyo (TSE: 4501) of Japan to co-develop and subsequently commercialize a treatment for gastro-esophageal reflux disease and peptic ulcers. The agreement focuses on Sankyo's CS-526 acid pump antagonist, which is currently entering Phase I clinical trials. The novel oral compound was discovered by Sankyo and Ube Industries, Ltd. (TSE: 4208). If successful, the new reversible acid pump antagonist class of drug may offer therapeutic advantages over existing antacid therapies, and may have the potential to achieve faster acid reduction and more durable activity, resulting in quicker symptom relief and ulcer healing. The program includes four alternative potential drug candidates.

Novartis will have exclusive worldwide rights to commercialize CS-526, or an alternative product, except in Japan and certain Middle East countries. Novartis and Sankyo will co-promote the product in the US and in most EU countries, whilst in some EU countries the two companies will co-market. Under the agreement, Sankyo will receive a signing fee and development and sales milestone payments. Sankyo also will receive royalties on product sales in countries other than co-promotion countries.

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Novartis and Sankyo will share equally all development costs as well as costs and profits of commercialization in co-promotion countries, while Ube will manufacture the drug substance.

If successful, the product would further enhance Novartis' presence in the gastro-intestinal therapeutic area, which has been considerably strengthened by the recent launch of Zelmac®/Zelnorm, an innovative treatment for irritable bowel syndrome.

### About GERD and peptic ulcer

Gastro-esophageal reflux disease and peptic ulcer are two of the most prevalent diseases in the western world and are the cause of significant patient suffering and healthcare costs.

GERD affects an estimated 5-7% of the global population men, women, and children. Persistent heartburn is the most frequent symptom but other effects include regurgitation, difficult or painful swallowing, sore throat or hoarseness, and wheezing in asthma patients. Peptic ulcers are associated with abdominal discomfort as well as weight loss, poor appetite, bloating, nausea, and vomiting.

### Disclaimer

This release contains certain "forward-looking statements," relating to the Company's business, which can be identified by the use of forward-looking terminology such as "new", "if successful", "may", "will" or similar expressions, or by discussions regarding the potential development and commercialization of CS-526 and alternative compounds. Such statements reflect the current views of

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the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There can be no guarantee that the agreement that is the subject of this release will lead to the commercialization of CS-526 or alternative compounds in any market. Any such commercialization can be affected by, among other things, uncertainties relating to product development and clinical trials, 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 materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

### About Sankyo

Sankyo Co. Ltd. is one of Japan's largest pharmaceutical companies, with annual worldwide sales of \$4.8 billion. Sankyo has a long history of discovering new classes of drugs. For further information about Sankyo, please consult <http://www.sankyo.co.jp>

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**Investor Relations Release**

**Enablex , Novartis' novel M3 antagonist for overactive bladder, on track for 2004 launch**

*Novartis receives approvable letter from FDA*

Basel, 3 October 2003 Novartis has received an approvable letter from the US Food and Drug Administration (FDA) for Enablex (darifenacin hydrobromide) for the treatment of overactive bladder. Acquired by Novartis in 2003, Enablex is an M3 selective receptor antagonist (M3 SRA), which works by selectively blocking an important receptor involved in the control of bladder muscle contraction. Novartis expects to launch the drug in 2004 after completing a limited amount of additional clinical work requested by FDA.

"Overactive bladder greatly impacts a person's ability to live a normal life. Sufferers often limit travel, social and work activities to avoid embarrassing situations that the condition can cause. Many patients go untreated, whilst those who do seek treatment are often unsatisfied with their medication," commented Joerg Reinhardt, Global Head of Development at Novartis.

The safety and efficacy of Enablex have been extensively studied in numerous pre-clinical studies and in more than 90 clinical trials involving more than 5000 patients. Pivotal studies explored key endpoints including the number of incontinence episodes per week, voluntary urination episodes (micturations) per day, episodes of urgency and average volume of urine passed per micturation. The first presentation of phase III clinical results for Enablex will take place next week at the International Continence Society's 33<sup>rd</sup> Annual Congress in Florence, Italy.

It is estimated that more than 17 million Americans experience bladder control problems, of which urge incontinence or overactive bladder is one of the most common. Caused by a problem with the bladder's detrusor muscle, overactive bladder is characterized by incontinence, urinary urgency and frequency, and nocturia (awakening at night to urinate). According to the American Foundation for Urologic Diseases, at least 16% of the population over the age of 40 suffer from chronic and troublesome symptoms of an overactive bladder. Although prevalence increases with age, the problem affects people of all ages, a large number of whom are under 65. As many as 30 to 50 percent of women over 50 are estimated to suffer from the condition. In many patients, a specific cause for the symptoms cannot be identified. As the population becomes increasingly older, the need and hence the market for safe and effective treatments continues to grow.

This release contains certain forward-looking statements relating to Novartis Pharma AG's business, which can be identified by the use of forward-looking terminology, such as "novel", "expects" and "after" or similar expressions, or by discussions of strategy, plans or intentions. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. Commercialization can be affected by, amongst other things, uncertainties relating to regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in

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general, as well as factors discussed in the Company's Form 20F 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.

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**SIGNATURES**



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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: November 3, 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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[FDA issues "approvable" letter for Certican® for heart and kidney transplantation in the US](#)

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