

NOVARTIS AG  
Form 6-K  
May 01, 2003

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 6-K

### REPORT OF FOREIGN PRIVATE ISSUER Pursuant to Rule 13a-16 or 15d-16 of the Securities Exchange Act of 1934

Report on Form 6-K for April 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

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2. Exelon® helps Alzheimer's disease patients to maintain greater independence
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8. New long-term data show Zometa® slows pain progression and reduces bone complications in advanced prostate cancer

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

### **Baseline data from VALIANT identifies risk factors that compromise survival after heart attack**

*Largest ARB trial in post-MI survival will report final results later this year*

Basel, 1 April 2003 New data show that 42% of all patients who are hospitalized for heart attack develop heart failure and/or left ventricular systolic dysfunction (LVSD) prior to their being discharged and that these patients are four times more likely to die in the hospital than heart attack patients who do not develop these complications ( $p < 0.001$ ). This finding is the first report from the VALIANT Registry, which tracked more than 5 500 patients who were consecutively hospitalized for myocardial infarction (MI, or heart attack) at 85 centers in nine countries. The abstract was presented at ACC '03 the 52<sup>nd</sup> Annual Scientific Session of the American College of Cardiology by Eric J. Velazquez, MD, Assistant Professor of Medicine in the Division of Cardiology, Department of Medicine, Duke University Medical Center in Durham, North Carolina.

The VALIANT Registry is adjunct to the VALLIANT trial (VALsartan In Acute myocardial iNfarcTion). VALIANT is the largest survival study with an angiotensin II receptor blocker (ARB) ever conducted in people who have experienced MI. The VALLIANT trial involves more than 14 500 patients from approximately 950 clinical sites in 24 countries. The primary investigator of VALIANT is Marc Pfeffer, MD, PhD, Professor of Medicine, Harvard Medical School, and Senior Physician, Brigham & Women's Hospital, Cardiovascular Division. VALIANT is sponsored by Novartis Pharma, AG, who has developed the ARB Diovan® (valsartan). While final results expected later this year, both the VALIANT Registry and baseline data from the overall trial are already adding insight into the treatment of people who have suffered heart attacks.

"VALIANT is already offering critical new insight into factors that complicate outcomes in post-MI patients," said Joerg Reinhardt, Head of Development, Novartis Pharma, AG. "Despite many available therapies, post-MI patients remain at high risk for recurring heart attacks, disabling stroke, heart failure and death. Better and earlier identification of those at high risk could lead to improved, more aggressive, and more targeted treatment approaches."

### **Likelihood of dying much higher in MI patients with diabetes**

Another key finding presented at ACC '03 the 52nd Annual Scientific Session of the American College of Cardiology, from the overall VALIANT study itself, is that the likelihood of dying was much higher in post-MI patients with diabetes than in patients who did not suffer from this disease (hazard ratio 1.2 [1.00, 1.46] 95% CI). VALIANT also showed that a significant percentage of patients hospitalized for acute heart attack were unknown to have diabetes (4% of study patients;  $p < 0.001$ ). Even though patients who were not aware they had diabetes were younger and had fewer clinical signs of heart disease (i.e., hypertension or dyslipidemia), their 30-day mortality rate was similar to patients who knew they had this disease before their heart attack. The abstract was presented by David Aguilar, MD, Research Fellow in Medicine, Department of Cardiovascular Medicine, Brigham and Women's Hospital, Boston, Massachusetts.

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### **Very elderly heart attack survivors not likely to receive aggressive treatment**

Presented by Harvey D. White, DSc, FACC, Director of Coronary Care and Cardiovascular Research, Green Lane Hospital, Auckland, New Zealand, another abstract based on VALIANT baseline data found that outcomes were worse in very elderly heart attack patients (75 years of age and older) with heart failure and/or left ventricular systolic dysfunction and that these patients were less frequently treated with aspirin, beta-blockers, or reperfusion therapy ( $p < 0.0001$ ). Similarly, additional baseline data from VALIANT presented by Robert M. Califf, MD, FACC, Professor of Cardiology, Division of Cardiology, Department of Medicine, Duke University Medical Center, showed that patients treated early with beta blockers were younger and were associated with lower mortality 30 days after patients were enrolled into the study (hazard ratio 0.74 [0.63-0.88] 95% CI).

### **About heart attack survivors**

On a worldwide basis, 7.3 million people die each year from heart attack.<sup>1</sup> According to the Framingham Heart Study, 25% of men and 38 percent of women die within one year following an initial recognized MI.<sup>2</sup> Within six years after a recognized heart attack, seven percent of men and six percent of women experience sudden death, 18 percent of men and 35 percent of women have another heart attack and 22% of men and 46% of women will be disabled by heart failure.<sup>2</sup> Heart failure is currently the fastest growing cardiovascular disease in the world and the most common reason why the elderly are hospitalized.<sup>3</sup> An estimated 20 million people worldwide suffer from this devastating condition.

### **About VALIANT**

VALIANT, a study of 14 500 post-MI patients, is investigating which treatment strategy is best for heart attack survivors: Diovan alone, the conventional agent captopril, or Diovan and captopril in combination. ACE inhibitors are recommended for treatment of post-heart attack patients along with several other types of drugs including aspirin and beta blockers. The population of VALIANT is roughly seven times larger than the individual populations of earlier pivotal placebo-controlled studies that established ACE inhibitors as a recommended post-MI treatment (i.e., SAVE, AIRE and TRACE). VALIANT is also investigating whether combination treatment with Diovan and captopril offers additional effects over treatment with captopril alone.

### **About Diovan**

Novartis' top-selling drug, Diovan is approved for first-line treatment of high blood pressure in the US and more than 80 other countries. Diovan is also the only ARB to be approved by the US Food and Drug Administration for the treatment of heart failure in patients who are intolerant of ACE inhibitors. Diovan is the leading ARB in the US, and is one of the fastest growing agents among the top 10 branded prescription antihypertensives on the market today.

Diovan is supported by the world's largest clinical trial program with an ARB, involving more than 45 000 patients, including 8 000 patients with diabetes. Besides VALIANT, several ongoing clinical trials are investigating new applications for Diovan across the cardiovascular disease continuum. These trials include VALUE (high-risk patients with hypertension), NAVIGATOR (patients with impaired glucose tolerance, or pre-diabetes, at high risk for cardiovascular events), and the recently completed VAL-HeFT, one of the largest studies ever completed in heart failure.

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1 American Heart Association. *International Cardiovascular Disease Statistics*. Dallas, TX. 2002.

2 American Heart Association. *Heart Disease and Stroke Statistics 2003 Update*. Dallas, TX. 2002.

3 National Heart, Lung and Blood Institute. *Data Fact Sheet*. Bethesda, MD. 2002.

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The foregoing release contains forward-looking statements that can be identified by terminology such as "baseline", "investigating", "new applications", or similar expressions, or by discussions regarding potential new indications or labeling for Diovan, or regarding the long-term impact of a patient's use of Diovan. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Diovan will be approved for any additional indications or labeling in any market. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Diovan could be affected by, among other things, additional analysis of Diovan clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of 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 COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Exelon® helps Alzheimer's disease patients to maintain greater independence**

*New findings suggest Exelon® significantly reduces decline in performance of activities of daily living in moderate to moderately severe Alzheimer's disease*

Basel, 3 April 2003 Therapy with Exelon® (rivastigmine) helps patients with moderate to moderately severe Alzheimer's disease (AD) to maintain greater independence, according to an analysis of nearly 1500 patients<sup>1</sup>.

The analysis, presented in Honolulu at the 55<sup>th</sup> annual meeting of the American Academy of Neurology, was unique in that it focused specifically on "activities of daily living" (ADLs). It showed that Exelon significantly reduced patients' loss of independence and that the best preserved activities were the ability to tell time, walk around without getting lost, use household appliances, dress appropriately, take normal precautions and display good eating behavior.

"These findings are important because they suggest treatment with Exelon helps preserve autonomy for patients, which in turn reduces the burden on their caregiver," said study co-author Rene Spiegel, Professor of Clinical Psychology at the University of Basel, Switzerland. "The larger differences seen in moderate and moderately severe patients extends findings in other studies<sup>ii</sup> showing that Exelon has a greater effect size in patients with more advanced AD. This may be due to the fact that Exelon uniquely inhibits the two enzymes involved in the breakdown of the neurotransmitter acetylcholine. The second of these enzymes, butyrylcholinesterase, seems to play an increasingly important role as the disease progresses," said Professor Spiegel.

#### **About the Analysis**

The analysis was based on data pooled from three multicenter, randomized clinical trials in which 1485 patients were given either Exelon (6-12 mg/day) or a placebo for 26 weeks. Participants were classified into mild, moderate or moderately severe AD.

The patients' abilities to perform ADLs were evaluated by means of the Progressive Deterioration Scale (PDS), a 29-item scale commonly used by caregivers to evaluate a patient's ability to perform common daily tasks. The researchers also identified the "six best preserved activity of daily living items" those that had the highest scores at the start of the study and could be considered the most important for day-to-day functioning.

Patients with moderate to moderately severe AD treated with placebo for 26 weeks showed a marked decline in the ability to perform ADLs, as measured by their total PDS and six-item PDS scores. This decline was significantly reduced among patients treated with Exelon.

Specifically, the decline in total PDS scores among these two groups for placebo vs. Exelon was 5.13 vs. 0.83 ( $p < 0.001$ ) and 5.2 vs. 1.46 ( $p < 0.05$ ), respectively. The decline in the six best preserved PDS ADLs items for these two groups was 5.18 vs. 1.04 ( $p < 0.001$ ) and 5.59 vs. 0.98 ( $p < 0.01$ ), respectively.

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For mild AD patients who, by definition, have little or no impairment in performance of ADLs there was only minimal decline on placebo and no statistically significant difference between Exelon and placebo over the 26 weeks of the study.

#### **About Exelon**

AD is associated with decreased transmission of signals between nerves in the brain, especially those that rely on the neurotransmitter acetylcholine. Many of the drugs used to treat AD work by preventing the breakdown of acetylcholine, thus prolonging its action. Exelon is unique in this class because it inhibits not just one but two key enzymes that break down acetylcholine: acetylcholinesterase and butyrylcholinesterase. Findings suggest that butyrylcholinesterase may play a greater role as AD progresses, and that the dual inhibitory action of Exelon may provide greater and more sustained efficacy.<sup>iii</sup>

#### **About Alzheimer's Disease**

AD is a progressive, degenerative disease that alters the brain, causing impaired memory, thinking and behavior. Affecting approximately 15 million people worldwide and 5 to 10 percent of those over 65 years of age, it is the most common form of dementia and the leading cause of death behind cardiovascular disease and cancer. It is associated with decreased transmission of signals between nerves in the brain, especially those that rely on the neurotransmitter acetylcholine.

The foregoing press release contains forward-looking statements, which can be identified by terminology such as "suggest", "may play", or similar expressions, or by express or implied statements regarding potential future sales or additional indications for Exelon as a result of the clinical trial described above. 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 clinical trial will result in any additional sales of Exelon, or in any additional indications for the in any market. Any such results can be affected by, amongst other things, uncertainties relating to 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 Novartis AG'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.

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(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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- i Feldman H, Spiegel R, Quarg P. An evaluation of the effects of rivastigmine on daily function in Alzheimer's disease at different levels of cognitive impairment. Poster presentation at: American Academy of Neurology 55<sup>th</sup> annual meeting, Honolulu, Hawaii, March 29-April 5, 2003.
- ii Doraiswamy PM, Krishnan KRR, Anand R, Sohn H, Danyluk J, Hartman RD, Veach J. Long-term effects of rivastigmine in moderately severe Alzheimer's disease: Does early initiation of therapy offer sustained benefits? *Prog Neuropsychopharmacol Biol Psychiatry* 2002;26(4):705-712.
- iii Ballard CG. Advances in the treatment of Alzheimer's disease: benefits of dual cholinesterase inhibition. *Eur Neurol* 2002; 47(1):64-70.

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### Investor Relations Release

#### **Elidel® cream 1% receives marketing authorization in Switzerland**

*Novartis' non-steroid eczema cream will be available from the beginning of April*

Basel, 7 April 2003 Novartis announced today that the Swiss Agency for Therapeutic Products (Swissmedic) has granted marketing authorization for the new non-steroid Elidel® (pimecrolimus) cream 1%. Elidel will be indicated in patients aged 2 years and over with mild-to-moderate atopic eczema, for the short-term treatment of signs and symptoms and intermittent long-term treatment.

Elidel cream is approved in Switzerland for patients for whom treatment with corticosteroids and emollients is not advisable<sup>1</sup>. The cream can be applied to all skin areas, including the most sensitive ones such as the face, neck and skin folds.

"Elidel is a long-awaited, steroid-free treatment for atopic eczema which affects up to 20%<sup>2</sup> of the population in Western countries, most of them children." said Thomas Ebeling, CEO Novartis Pharma. "The cream is a major breakthrough for both the patients suffering from this debilitating disease and the healthcare professionals who are treating them."

The approval in Switzerland is based on clinical trials involving more than 2000 patients, which have shown that Elidel cream offers effective control of atopic eczema without the risk of steroid-associated side effects such as skin thinning<sup>3</sup>. The cream has been proven to relieve itch the most bothersome symptom of eczema within three days of treatment. When used at the first signs of itching or redness of the skin, Elidel has been shown in one-year studies to prevent progression to severe flares in up to 51% of patients, and to eliminate the need for topical corticosteroid treatment in up to 57% of patients (children aged 2-17 years and adults).<sup>4,5</sup>

#### **About Elidel**

Discovered by the Novartis Research Institute in Vienna, Austria, Elidel contains the active ingredient pimecrolimus, which is derived from ascomycin, a natural substance produced by the bacterium *Streptomyces hygroscopicus* var. *ascomyceticus*. Pimecrolimus selectively blocks the production and release of inflammatory cytokines from T-cells in the skin. It is these cytokines which trigger processes leading to the

inflammation, redness and itching associated with eczema.<sup>6</sup>

Elidel is now approved in 48 countries and is launched in 20 countries world wide, including the US and major European markets. It has received recommendation for approval from the Netherlands, Sweden, and Norway as the result of a repeat use Mutual Recognition Procedure.

This press release contains forward-looking statements which can be identified by the use of forward-looking terminology such as "will be", "recommendation for approval", or similar expressions,

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or by express or implied statements regarding the potential for additional sales of Elidel as a result of this new approval, or regarding potential approvals of Elidel in additional markets. 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 approval will result in any particular level of additional revenue, or that Elidel cream will be commercialized in any additional markets. Any such results can be affected by, amongst other things, uncertainties relating to 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 Novartis AG's Form 20-F filed with the US Securities and Exchange Commission. Any of these and other factors can cause the actual results to differ materially from the expected or predicted results.

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- 1 Arzneimittel-Kompodium der Schweiz Supplementum 4/2003
  - 2 Leung D, et al. Atopic dermatitis. Lancet 2003;361:151-60
  - 3 Queille-Roussel C, et al. The new topical ascomycin derivative SDZ ASM 981 does not induce skin atrophy when applied to normal skin for 4 weeks: a randomized, double-blind controlled study. BJD 2001;144:507-513
  - 4 Meurer M, et al. Pimecrolimus cream in the long-term management of atopic dermatitis in adults: a six-month study. Dermatology 2002;205:271-277
  - 5 Wahn U, et al. Efficacy and safety of pimecrolimus cream in the long-term management of atopic dermatitis in children. Pediatrics 2002;110(1)
  - 6 Stuetz A, Grassberger M, Meingassner J. Pimecrolimus (Elidel, SDZ ASM 981) Preclinical pharmacologic profile and skin selectivity. Seminars in cutaneous medicine and surgery 2001;20(No 4):233-241

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**Investor Relations Release**

**Novartis wins important ruling against GlaxoSmithKline and continues  
to market generic versions of Augmentin® in US**

Basel, 9 April 2003 The Novartis Group has won an important ruling in its legal dispute with GlaxoSmithKline (GSK) concerning AmoxC (amoxicillin/clavulanic acid), the Group's generic version of GSK's top-selling antibiotic Augmentin. GSK had sought an order to prevent Novartis affiliates from importing and selling AmoxC in the US, claiming that the affiliates used a proprietary GSK strain of bacteria to manufacture the generic product. An Administrative Law Judge of the US International Trade Commission (ITC) dismissed GSK's claims and decided that the strain is not entitled to trade secret protection. He stated that the strain lost any trade secrecy protection that it may have had when GSK entered into a prior settlement agreement with Novartis' subsidiary Biochemie.

Christian Seiwald, worldwide Head of Novartis' Generics Business Unit commented: "We are very pleased with the judge's ruling, which supports our affiliate in continuing to provide high quality generic alternatives to patients in the US. It is our firm conviction that we have acted correctly and ethically throughout."

In May 2002, in a suit brought by Novartis' subsidiary Geneva Pharmaceuticals against GSK, the US District Court for the Eastern District of Virginia rendered a decision that invalidated GSK's remaining patents covering Augmentin. Following that ruling, Geneva was the first to launch a generic version of Augmentin in the US, the world's biggest pharmaceutical market, in July 2002.

GSK has appealed both the decision of the District Court and that of the ITC Administrative Law Judge.

This release contains certain "forward-looking statements," relating to the Group's business, which can be identified by express or implied statements regarding the likelihood of the Novartis Groups final success in its litigation with GSK, and regarding its future ability to sell AmoxC in the US. 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. Such risks include the possibility that the Administrative Law Judge's ruling is not affirmed on appeal, the risks of collateral litigation, market place risks that could adversely affect Geneva Pharmaceutical's ability to market AmoxC in the US as well as the other factors discussed in Novartis AG'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.

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**Investor Relations Release**

**Novartis and Schering-Plough plan joint development of a fixed inhaled combination of Foradil® and Asmanex® for asthma and COPD**

Basel, 10 April 2003 Novartis Pharma AG has signed a license agreement with Schering-Plough to jointly develop and market worldwide a new combination product for the treatment of asthma and chronic obstructive pulmonary disease (COPD). The new product will combine Novartis' Foradil® (formoterol fumarate), a selective, long-acting beta<sub>2</sub>-agonist, with Schering-Plough's Asmanex® (mometasone furoate), an inhaled corticosteroid. These will be combined in a single inhalation device for the convenience of patients. Terms of the agreement are not being disclosed.

"Many people recognize that the incidence of asthma is steadily increasing. More than 100 million people worldwide are newly diagnosed with asthma each year according to GINA (Global Initiative For Asthma). Few people are aware of the fact that asthma patients still die of exacerbations. According to the US National Center for Health Statistics, asthma caused almost 4 500 deaths in the USA in 2000. In the case of COPD the death rate has risen substantially over the past 40 years, with over 120 000 deaths in the USA in 2000," said Thomas Ebeling, CEO of Novartis Pharma. "In addition to the loss of life," Ebeling noted, "the daily effect of respiratory disease on patients and their families is incalculable. This agreement with Schering-Plough is one more example of Novartis' commitment to the development of novel products for patients suffering from respiratory diseases. Combining the therapeutic benefits of Foradil and Asmanex in a single device will significantly enhance the ability of doctors to control asthma and COPD symptoms".

Foradil is indicated for the maintenance treatment of asthma and COPD, and the acute prevention of exercise-induced bronchospasm. It is widely used in 87 countries around the world.

Asmanex Twisthaler® (mometasone furoate Dry Powder Inhaler) is currently approved in 30 countries as therapy in the control and management of mild, moderate or severe persistent asthma in patients 12 years of age and older. Asmanex Twisthaler is being launched in the European Union (EU); additional marketing applications for Asmanex Twisthaler are currently undergoing regulatory review in other countries worldwide, including the United States.

Combination products containing inhaled corticosteroids and long-acting beta<sub>2</sub>-agonists are the fastest growing segment of the worldwide asthma market (according to IMS data).

In November 2002, Schering-Plough and Novartis announced an agreement granting Schering-Plough exclusive US distribution and marketing rights to Novartis' Foradil® Aerolizer® (formoterol fumarate inhalation powder).

The foregoing press release contains forward-looking statements that can be identified by forward-looking terminology such as "plan", "new", "will" or similar expressions, or by express or implied discussions regarding the potential development and approval of a Foradil/Asmanex combination product, or regarding potential revenues from future sales of such a combination product. Such 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. There can be no guarantees that the aforementioned agreement will result in the approval of the planned combination product in any market, or in any additional sales of Foradil or Asmanex. Any such sales or other results can be affected by, amongst other things, uncertainties relating to product development, clinical trials and product efficacy, 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 Novartis AG's Form 20-F filed with the Securities and Exchange

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Commission. Any of these and other factors can cause the actual results to differ materially from the expected or predicted results.

Schering-Plough is a research-based company engaged in the discovery, development, manufacturing and marketing of pharmaceutical products worldwide.

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### Investor Relations Release

#### **New immunosuppressant Certican outperforms azathioprine in lung transplant patients**

*Novel Novartis drug Certican has been shown to target many of the underlying causes of chronic allograft dysfunction or late graft loss*

Basel, 14 April Certican (everolimus) is a novel, investigational immunosuppressant drug in its final stages of development. It has proved significantly more effective than azathioprine in preventing acute rejection and preserving pulmonary function in lung and heart/lung transplant patients. The data was presented in Vienna to delegates at the International Society for Heart and Lung Transplantation 23rd Annual Meeting and Scientific Sessions, 9-12 April.

Preventing acute rejection, and maintaining pulmonary function, is a major unmet medical need in lung transplantation. Described as a "proliferation inhibitor", Certican has been shown to target many of the underlying causes of chronic allograft dysfunction or late graft loss, including acute rejection and vascular remodelling.

In one of the largest global trials of its kind, over 200 patients from 33 centres in nine countries took part in the randomised, double-blind phase III study which is planned to last three years. Results at 12 months showed:

22% of patients receiving Certican 1.5mg/bid reached the composite primary study endpoint (>15% decline in pulmonary function, graft loss or patient death) compared with 34% of patients receiving azathioprine (1.0 - 3.0 mg/kg/day) (p 0.0455)

Certican was superior to azathioprine in terms of the number of acute rejection episodes requiring treatment (8% with Certican; 32% with azathioprine; p <0.001)

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Certican was superior to azathioprine in terms of the single endpoint of more than 15% reduced pulmonary function (16% of patients vs 28% respectively; p 0.034)

All patients received standard immunosuppressive therapy with full dose Neoral® (cyclosporin for microemulsion) with or without corticosteroids.

Lead investigator, Associate Professor Gregory Snell commented: "Decline in pulmonary function is a common and problematic occurrence after lung transplantation. Principal causes include acute rejection and chronic allograft dysfunction, which manifests in lung transplant patients by obliteration and loss of the small bronchioles. There is an urgent need for immunosuppressive regimens with the capacity to address this complication and the impressive performance of Certican in this regard is very encouraging."

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At the same meeting, 24 month results of adjunctive Certican versus azathioprine in a major international trial of over 600 heart transplant patients were presented. These data confirmed the superiority of Certican over azathioprine in terms of all-cause efficacy failure, acute rejection rates and cardiac allograft vasculopathy which is known to contribute to late graft loss or chronic allograft dysfunction.

It is conceivable that these attributes of Certican could have a major impact on both health-related quality of life for transplant patients and on medical care resource utilisation by decreasing morbidity, graft loss and the expense associated with prolonged hospitalisation and/or re-transplantation.

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", "novel", "investigational... drug", "final stages of development", "conceivable", "could have", or similar expressions, or by express or implied discussions regarding the potential 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.

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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### 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 (cyclosporin microemulsion) is the mainstay of immunosuppression in transplant patients, permitting long-term survival, but the risk of acute and chronic graft rejection persists. Rates of chronic allograft dysfunction or late graft loss in particular have been barely influenced by standard regimens. Identifying additional immunosuppressive agents which can act synergistically with Neoral is therefore an urgent priority in transplantation research.

Some degree of chronic allograft dysfunction (also known as obliterative bronchiolitis) occurs in up to 50% of lung transplant patients who survive at least five years (compared to 23% for living donor kidney transplantation). The only factor clearly shown to predispose patients to the development of obliterative bronchiolitis is the number/severity of acute rejection episodes.

Certican is being fully assessed in Phase III trials in kidney transplant patients, in heart transplant patients and now in lung and heart/lung transplant patients.

For further information, please access the Virtual Press Office on <http://www.transplantsquare.com>.

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**Media Release    Communiqué aux Médias    Medienmitteilung**

**Novartis launches international education program to ensure effective treatment with its fixed dose combination anti-malarial drug product, consisting of artemether and lumefantrine (Coartem®)**

*"Coartem and Malaria" initiative is latest step in the collaboration with WHO to provide this drug at cost to patients in developing countries*

*Launch of program underlines Novartis' commitment to access to medicines for tropical diseases*

Basel, 25 April 2003 Novartis announced today the introduction of its international malaria education program, "Coartem and Malaria", developed in collaboration with the World Health Organization (WHO) in support of the effort to Roll Back Malaria. This education program addresses a serious problem facing many malaria victims in developing countries: how to take their medicine correctly. Many patients in developing countries have difficulty reading conventional Western style packaging which tragically leads to the inappropriate use of anti-malarial drugs, poor cure rates and avoidable deaths.

The "Coartem and Malaria" education program supports Novartis' novel product packaging, which has been specially designed to improve patient compliance in developing countries, optimizing drug response and cure rates. The innovative packaging incorporates a series of simple visual images that depict correct use of the six-dose regimen for infants, children and adults. Both the packaging and educational program have undergone intensive field testing.

"Coartem and Malaria" has been intensively tested and validated in the countries where it is most needed. The intention is to ensure effective treatment of one of the world's major killers," said Dr. Daniel Vasella, CEO and Chairman of Novartis. "This important education initiative confirms Novartis' commitment to the concept of public/private partnerships, the cornerstone of the U.N. Global Compact. The program marks another milestone in Novartis' and RBM's shared goal of saving people, many of them children, from malaria and it underlines Novartis' commitment to access to medicine for tropical diseases," Dr. Vasella concluded.

More than 300 million acute cases of malaria illness occur worldwide each year resulting in at least 1 million deaths.<sup>1</sup> The majority of victims are children and an estimated 90% of these deaths occur in Africa.<sup>1</sup> The availability of the fixed dose combination consisting of artemether and lumefantrine at cost to national governments and anti-malarial programs of non-governmental organizations with distribution through WHO represents an important contribution to the fight against one of the world's leading killers.

Coartem® is the first fixed-dose artemisinin-based combination malaria treatment available. Prior to the introduction of artemisinin combination therapy (ACT), inappropriate drug use in developing countries had led to the emergence of drug-resistant parasites. In some regions malaria threatened to become untreatable. To date, no clinical resistance has been documented against artemisinins, further strengthening the argument for the artemether/lumefantrine combination which has demonstrated cure rates above 95% even in most areas of multi-drug resistance.<sup>2</sup>

By creating the education program, Novartis aims to further support a very effective and well tolerated anti-malarial treatment, making an important contribution to health and well-being in developing countries. The primary aim of the education program is to communicate the importance of closely adhering to the dosage recommendations. It comprises an easy to understand training manual, instruction cards and posters. These explain what malaria is and how it spreads and give an explicit graphic message about how Coartem should be taken to achieve optimum cure rates.

Validated and endorsed by operational field research, the education package is intended for use by paramedical staff and by authority figures in rural communities, such as school teachers, care-givers and village elders. Field research and development was carried out in cooperation with the UNDP World Bank WHO Special Programme for Research and Training in Tropical Diseases. Introduction will begin in countries that have adopted artemether/lumefantrine in their treatment policies. Further roll out will follow as more countries begin using Coartem in their public-sector health facilities.

Novartis has committed itself to the principles of the Global Compact and has already made significant contributions by providing Coartem at cost through WHO, by donating drugs to eliminate leprosy world-wide, and by establishing the Novartis Institute for Tropical Diseases in Singapore, where research activities are expected to provide synergies with the Novartis Tropical Medicine product portfolio.

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For further information about malaria, please visit [www.malariaandhealth.com](http://www.malariaandhealth.com) References

1. Roll Back Malaria, "What is malaria", RBM Infosheet 1 of 11, March 2002.
2. van Vugt M et al. Artemether-lumefantrine for the treatment of multidrug-resistant falciparum malaria. Transactions of the Royal Society of Tropical Medicine and Hygiene (2000) 94: 545-548.

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**Media Release    Communiqué aux Médias    Medienmitteilung**

### **New long-term data show Zometa® slows pain progression and reduces bone complications in advanced prostate cancer**

Basel, Switzerland, 30 April 2003 Zometa® (zoledronic acid) treatment of patients with prostate cancer that has spread to bone significantly lowers the risk of debilitating bone complications and delays their onset by a median time of more than five months. In addition, increases in pain scores were consistently lower for patients on Zometa than for those on placebo, according to data presented today during the annual meeting of the American Urological Association (AUA) in Chicago, Illinois, USA.

Research indicates that 65% to 75% of all patients with advanced prostate cancer develop bone metastasis, the spread of cancerous cells from the original tumour to bones. Often, bone is the only site of metastasis in these patients. Complications resulting from bone metastases

include, among others, bone pain, pathologic fractures, a need for radiation or surgery to bone, spinal cord compression, change of antineoplastic therapy to treat bone pain and hypercalcaemia. These painful, debilitating complications can significantly impact the daily lives of patients and caregivers. A recently published analysis indicates that skeletal fractures in patients with prostate cancer can correlate with decreased survival. Zometa is the first and only bisphosphonate indicated for prostate-related bone metastases.

"The lives of patients with advanced prostate cancer and complications from bone metastases are often typified by severe pain and an inability to carry out daily activities," said Fred Saad, M.D., lead investigator and Associate Professor of Urology and Director of Urologic Oncology at the Montreal Cancer Institute, University of Montreal, Canada. "These findings demonstrate Zometa may reduce the risk of bone complications and their pain progression. The resulting improvement may reduce the stress and burden both patients and their caregivers experience on a daily basis."

### **Study Details Design**

The multicenter, randomised, placebo-controlled trial was conducted in 643 patients with advanced prostate cancer and at least one site of bone metastasis. Of the 643 patients, 208 completed the 15-month core phase, and 186 of them continued to receive double-blind study medication during an extension phase.

### **Bone Complications**

After 24 months of treatment, only 38% of patients in the Zometa group had experienced a bone complication (also called a skeletal-related event, or SRE). By contrast, 49% of patients in the placebo group (P=0.028) developed SREs.

In addition, when compared to placebo, Zometa significantly delayed the time to the first bone complication, the median time was delayed by more than five months (median, 488 days vs. 321 days for placebo, P=0.009), and also significantly delayed the time to the first pathologic fracture. Zometa also significantly reduced the skeletal-morbidity rate (mean, 0.77 vs. 1.47 events/year for placebo,

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P=0.005). A skeletal- morbidity rate is the ratio of the number of skeletal complications over a defined period time.

The study also included a multiple event analysis, which showed that Zometa reduced the overall risk of developing an SRE by 36% (hazard ratio= 0.64; 95% confidence interval [CI] 0.49; 0.85; P=0.002). This means that patients' risk of developing one or more complications, such as fractures, while on Zometa was significantly reduced.

### **Bone Pain**

Zometa consistently reduced the rate of pain score increases over the entire 24 months that patients were in the study, as assessed by the Brief Pain Inventory (BPI) at baseline and at six-week intervals. This is the first demonstration of durable effect on bone pain achieved with bisphosphonate therapy in patients with prostate cancer metastatic to bone.

### **About Zometa**

Novartis has received marketing authorization for Zometa in more than 60 countries, including the member states of the European Union and the United States, 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 tumours. Novartis also has received marketing clearance for Zometa in the treatment of tumour-induced hypercalcaemia (TIH), also known as hypercalcaemia of malignancy (HCM), in more than 80 countries throughout the world. To date, it is estimated that more than 300,000 patients worldwide have received Zometa treatment.

### **Contraindications and Adverse Events**

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.

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 "show", "significantly lowers risk," "delays onset," "can significantly impact", "can correlate", "may reduce," or similar expressions, or by discussions regarding potential new indications for Zometa, or regarding potential future sales 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 potential future sales 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 Zometa could be affected by, among other things, additional analysis of Zometa clinical data; new clinical data;

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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 Securities and Exchange Commission of the United States. 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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#### 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 30, 2003

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: *Head Group Financial Reporting and Accounting*

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### ENCLOSURES

Baseline data from VALIANT identifies risk factors that compromise survival after heart attack

Exelon® helps Alzheimer's disease patients to maintain greater independence

Elidel® cream 1% receives marketing authorization in Switzerland

Novartis wins important ruling against GlaxoSmithKline and continues to market generic versions of Augmentin® in US

Novartis and Schering-Plough plan joint development of a fixed inhaled combination of Foradil® and Asmanex® for asthma and COPD

New immunosuppressant Certican outperforms azathioprine in lung transplant patients

Novartis launches international education program to ensure effective treatment with its fixed dose combination anti-malarial drug product, consisting of artemether and lumefantrine (Coartem®)

New long-term data show Zometa® slows pain progression and reduces bone complications in advanced prostate cancer

### SIGNATURES