

NOVARTIS AG  
Form 6-K  
June 03, 2004

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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 May 2004  
(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:

Enclosures:

1. New clinically important BP efficacy data with Novartis' antihypertensives Diovan® and Co-Diovan® presented at leading hypertension meeting (New York, 21 May 2004)

- 2.

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MorphoSys and Novartis Forge Strategic Antibody Alliance (Martinsried/Munich (Germany) and Cambridge, MA (USA), May 19, 2004)

3. Single dose of Zoledronic acid yields significantly higher, faster response rates than standard Paget's disease therapy, new study shows (Basel, 18 May 2004)
  4. Sandoz strengthens global production network with three new facilities (Vienna, May 18, 2004)
  5. Novartis marks 20 years of improving patients' lives with innovative treatments for transplantation (Basel, 14 May 2004)
  6. Novartis confirms commitment to new markets of the European Union with major investment in Poland (Stryków, 12 May 2004)
  7. Visudyne® launched in Japan for treatment of age-related macular degeneration (Basel, 10 May 2004)
  8. Novartis files Femara applications in North America and Europe for indication as first ever post-tamoxifen treatment for early breast cancer (Basel, 10 May 2004)
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**INVESTOR RELATIONS RELEASE**

**New clinically important BP efficacy data with Novartis' antihypertensives Diovan® and Co-Diovan® presented at leading hypertension meeting**

*Study results show excellent BP efficacy reduction with Co-Diovan in difficult-to-treat patient population*

New York, 21 May 2004 Novartis' Co-Diovan® (valsartan and hydrochlorothiazide) aggressively lowers blood pressure to recommended target goals as effectively as amlodipine but with fewer side effects in African Americans, considered a difficult-to-treat patient population. The study called AADVANCE (African American Diovan (Valsartan) Amlodipine (Norvasc®<sup>1</sup>) Clinical Efficacy Trial), was among several new studies examining the efficacy of Diovan® (valsartan) and Co-Diovan presented this week during the American Society of Hypertension 19<sup>th</sup> Annual Scientific Meeting and Exposition in New York.

High blood pressure is a public health crisis. One billion people worldwide suffer from high blood pressure, which accounts for one in four adults or one-sixth of the world's population. As a result of genetic and other factors, high blood pressure is often difficult to treat in African Americans, particularly in those who also have diabetes. According to new treatment guidelines,<sup>2,3</sup> most of these patients need more than one type of high blood pressure treatment to achieve healthy blood pressure levels.

Despite proven cardiovascular benefits, inhibitors of the renin-angiotensin-system (RAS) angiotensin II receptor blockers (ARBs) and angiotensin-converting-enzyme (ACE) inhibitors are underused in the African American population. "The compelling new data in the AADVANCE study and the other studies presented add to the cumulative clinical evidence of the wide range of benefits that Diovan and Co-Diovan provide in terms of double-digit blood pressure lowering, superior tolerability, long-term patient persistency with therapy, and cardioprotection, further demonstrating that Diovan and Co-Diovan offer a new standard of care in cardiovascular disease," said Joerg Reinhardt, Head of Development, Novartis Pharma AG.

A leading fixed-dose combination of two effective anti-hypertensive medicines from Novartis, Co-Diovan combines a diuretic and Diovan in a convenient once-a-day tablet. Diovan, the fastest growing branded antihypertensive globally, blocks the RAS, a hormonal system that regulates blood pressure and which can have harmful effects on the heart and blood vessels. Diovan not only powerfully lowers blood pressure, but is known to have additional positive effects beyond lowering blood pressure. In fact, Diovan is proven to have all of the life-saving and other established benefits of ACE inhibitors in patients following a heart attack. In addition to hypertension, Diovan is also available in more than 40 countries for the treatment of heart failure in patients who also take usual therapy including diuretics, digitalis and either beta blockers or angiotensin converting enzyme (ACE) inhibitors, but not both.

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<sup>1</sup> *Norvasc® is a registered trademark of Pfizer Inc.*

#### **About AADVANCE**

AADVANCE was a prospective, double-blind, randomised, head-to-head comparison of Co-Diovan and amlodipine, a calcium channel blocker, in 482 African Americans with mild to moderate high blood pressure ( $\geq 140$  and  $\leq 180$  mmHg/ $\geq 90$  and  $\leq 110$  mmHg). After a 2-3 week placebo run-in, patients were randomised to Diovan 160 mg monotherapy or amlodipine 5 mg for 2 weeks, and then force-titrated to Co-Diovan 160/12.5 mg or amlodipine 10 mg for an additional 10 weeks. AADVANCE showed Co-Diovan reduced blood pressure as effectively as amlodipine (mean reduction in 24-hr ABPM systolic BP  $-15.9 \pm 12.1$  mmHg vs.  $-14.5 \pm 12.2$  mmHg and diastolic BP  $-10.2 \pm 8.6$  mmHg vs.  $-9.1 \pm 8.3$  mmHg respectively;  $p < 0.0001$ ) but was significantly less likely to cause peripheral oedema (leg swelling) (1.7% vs. 5.8% respectively;  $p = 0.0309$ ) or joint swelling (0% vs. 2.9% respectively;  $p = 0.0082$ ). The incidence of other adverse events was similar between groups.

Several previous studies have also shown Diovan has proven efficacy and tolerability and additional benefits in relation to amlodipine. Val-Syst, for example, showed Diovan was as effective as amlodipine in lowering isolated systolic hypertension in the elderly, but it was much less likely to cause peripheral oedema ( $p < 0.0001$ ).<sup>iii</sup>

VALUE (Valsartan Antihypertensive Long-term Use Evaluation Trial) is also exploring the differential effects of Diovan-based therapy vs. amlodipine-based therapy in 15,313 hypertensives at high-risk for cardiovascular events because of at least one other co-existing disease or risk factor (e.g., diabetes, history of stroke, high cholesterol, angina). VALUE is designed to discover whether, in high-risk patients with the same level of blood pressure control, Diovan-based therapy has additional effects on cardiovascular outcomes such as heart attack, heart failure and stroke. The findings of VALUE will be reported at the 14<sup>th</sup> European Meeting on Hypertension in Paris on June 14, 2004.

#### **About VALOR**

Another study presented at ASH also reinforces why Diovan and Co-Diovan are leading choices in the treatment of hypertension and specifically, the benefits of combination therapy for those patients who require more than one type of high blood pressure treatment to reach target systolic blood pressure goals. VALOR was an eight-week, multicentre, randomised, double-blind, active controlled study at 30 sites in Canada with 767 patients. VALOR evaluated patients with moderate to severe high blood pressure (systolic blood pressure  $\geq 160$  mmHg and  $\leq 200$  mmHg) first on Diovan 160 mg monotherapy and then titrated up to Co-Diovan 160/12.5 mg or 160/25 mg. Mean systolic blood pressure at baseline was 167.9 mmHg. Diovan 160 mg demonstrated excellent tolerability and blood pressure reductions from baseline (mean change:  $-20.7$ ). Titration to Co-Diovan 160/12.5 mg and 160/25 mg provided significant additional reductions in systolic blood pressure (mean change:  $-27.9$  and  $-28.3$ , respectively) with no increase in adverse events with titration to Co-Diovan.

#### **About ABCD-2V**

In addition to AADVANCE and VALOR, data from the ABCD-2V trial was presented at this meeting. This study was a single-centre, prospective, randomised trial investigating the long-term effects of moderate versus intensive blood pressure control on the progression or development of complications in type 2 diabetic patients. Patients were randomised to receive either "intensive" blood pressure control with Diovan plus additional antihypertensives to achieve a target diastolic blood pressure of  $< 75$  mmHg or "moderate" blood pressure control with placebo (target diastolic blood pressure goal:  $< 80-90$  mmHg). The average length of patient follow-up was 1.9 years. Mean blood pressure of 119 7.8/78 3.1 mm Hg was achieved in the intensive group and 124 6.8/81 4.1 mm Hg in the moderate group. A higher percentage of patients (77.8%) returned to normoalbuminuria with intensive than with moderate therapy (33.3%;  $p = 0.046$ ). There was no difference in change in creatinine clearance between treatment groups.

AADVANCE, VALOR, VALUE and ABCD-2V are part of the Diovan clinical trial programme, one of the world's largest cardiovascular research programmes. The programme involves more than 50,000 patients, including 9,500 patients with diabetes, in major trials investigating potential new applications for Diovan across the cardiovascular disease continuum. Already completed Diovan trials include VALIANT in post-heart attack patients and Val-HeFT in heart failure patients. Ongoing or soon to be reported trials include VALUE, also NAVIGATOR in pre-diabetes patients at risk for cardiovascular disease and Val-MARC, a study of the effects of Diovan on C-reactive protein, an inflammatory marker for heart disease.

The foregoing release contains forward-looking statements that can be identified by terminology such as "soon to be reported" or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Diovan or Co-Diovan, or regarding potential future revenues from Diovan or Co-Diovan. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan and Co-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 or Co-Diovan will be approved for any additional indications or labelling in any market, or that they will reach any particular levels of revenue. In particular, management's expectations regarding Diovan and Co-Diovan could be affected by, among other things, additional analysis of Diovan or Co-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; governmental and other 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 materialise, 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 2003, the Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 500 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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1 The Seventh Report of the Joint National Committee of Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. JNC 7 EXPRESS.

1 Hypertension in African Americans Working Group. Management of high blood pressure in African Americans: consensus statement of the Hypertension in African Americans Working Group of the International Society on Hypertension in Blacks. Arch Intern Med. 2003.

1 Malacco E. The efficacy and safety of valsartan-based versus amlodipine-based treatment in elderly patients with isolated systolic hypertension: the Val-Syst study. (Abstract presented at the American Society of Hypertension 18<sup>th</sup> Annual Meeting and Exposition, May 2003)

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**PRESS RELEASE**

Martinsried/Munich (Germany) and Cambridge, MA (USA), May 19, 2004

**MorphoSys and Novartis Forge Strategic Antibody Alliance**

*Novartis Steps up Therapeutic Antibody Research*

MorphoSys AG (Frankfurt Stock Exchange: MOR; Prime Standard Segment) and Novartis AG (NYSE: NVS) today announced a significant strategic collaboration to discover and develop antibody-based biopharmaceuticals as therapeutic agents, in order to address unmet medical need across a variety of diseases. MorphoSys brings validated and robust human antibody technologies (HuCAL GOLD®) to Novartis' new strategic research directions, building a collaboration that will identify and develop novel therapeutic agents rapidly and efficiently.

"Novartis is committed to therapeutic antibodies as key weapons in the medical armamentarium alongside small molecule drugs. We believe that these antibodies will become increasingly important components of our already strong pipeline in order to better address unmet medical needs with innovative medicines across a variety of diseases. We have chosen MorphoSys as the ideal partner for this element of our strategy because of their highly differentiated technology, which we believe will significantly strengthen and accelerate our antibody research," stated Dr. Mark Fishman, President of the Novartis Institutes for BioMedical Research.

MorphoSys scientists will work directly with Novartis scientists across the global sites of the Novartis Institutes for BioMedical Research (NIBR), including the new world headquarters in Cambridge, MA, USA. The MorphoSys HuCAL GOLD® technology will be an integral part of Novartis' drug discovery and development efforts, with the goal of identifying and developing multiple HuCAL GOLD®-derived therapeutic antibodies against many different targets. During the three year term of the agreement, which may be extended up to a total of five years, Novartis will fund internal research at MorphoSys that will generate and optimize HuCAL GOLD® antibodies against targets identified by Novartis. In addition, Novartis will have access to the current MorphoSys HuCAL GOLD® library at two of its sites. This technology, in conjunction with Novartis' leading research and development capabilities, will potentially enable Novartis to shorten the time needed to generate novel therapeutic as well as research antibodies.

Additionally, under the terms of this collaboration Novartis will be MorphoSys' first partner to receive a non-exclusive option on internalization of the entire MorphoSys technology platform, which would trigger an additional payment by Novartis to MorphoSys.

Underscoring the strategic nature of the collaboration, Novartis will make an approx. € 9 million investment in MorphoSys by purchasing non-interest bearing convertible bonds of MorphoSys. The convertible bonds can be converted into 490,133 common MorphoSys shares, to be issued from conditional capital. In addition, MorphoSys will receive over US\$ 30 million in committed R&D funding and technology license fees over the first three years. MorphoSys also stands to receive technology license payments, research and developmental milestones, as well as royalties on marketed antibody products.

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"This is our largest collaboration to date. We are delighted to see our HuCAL® technology become an integral part of drug development at Novartis," commented Dr. Simon Moroney, Chief Executive Officer of MorphoSys AG. "Building on the strengths of both companies, this collaboration will focus on the seamless transition of HuCAL® antibodies from target validation tools to optimized human therapeutic products. Together with Novartis, we will apply the HuCAL® technology on a large scale in treating disease."

### About MorphoSys:

MorphoSys develops and applies innovative technologies for the production of synthetic antibodies, which accelerate drug discovery and target characterization. Founded in 1992, the Company's proprietary Human Combinatorial Antibody Library (HuCAL®) technology is used by researchers worldwide for human antibody generation. The Company currently has licensing and research collaborations with Bayer (Berkeley, California/USA), Biogen Idec Inc. (Cambridge, Massachusetts/USA), Boehringer Ingelheim (Ingelheim, Germany), Bristol-Myers Squibb (Wilmington, Delaware/USA), Centocor Inc. (Malvern, Pennsylvania/USA), GPC Biotech AG (Munich/Germany), Hoffmann-La Roche AG (Basel/Switzerland), ImmunoGen Inc. (Cambridge, Massachusetts/USA), Oridis Biomed GmbH (Graz/Austria), Pfizer Inc. (Delaware/USA), ProChon Biotech Ltd. (Rehovot/Israel), Schering AG (Berlin/Germany) and Xoma Ltd. (Berkeley, California/USA). For further information please visit the corporate website at: <http://www.morphosys.com/>.

*Statements included in this press release which are not historical in nature are intended to be, and are hereby identified as, "forward-looking statements" for purposes of the safe harbour provided by Section 21E of the Securities Exchange Act of 1934, as amended by the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by words including "anticipates", "believes", "intends", "estimates", "expects" and similar expressions. The company cautions readers that forward-looking statements, including without limitation those relating to the company's future operations and business prospects, are subject to certain risks and uncertainties that could cause actual results to differ materially from those indicated in the forward-looking statements. Factors that may affect future operations and business prospects include, but are not limited to, clinical and scientific results and developments concerning corporate collaborations and the company's proprietary rights and other factors described in the prospectus relating to the company's recent public offering.*

### About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's business achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78, 500 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.



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 "will present", "potential... to enhance", "provide treatment options", "committed to developing", "to maintain", or similar expressions, or by express or implied discussions regarding the potential development and commercialization of new products or regarding potential future sales from any such products. 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. Any such commercialization or sales 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 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.

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**INVESTOR RELATIONS RELEASE**

**Single dose of Zoledronic acid yields significantly higher, faster response rates than standard Paget's disease therapy, new study shows**

*First filing for zoledronic acid in metabolic bone disease*

**Basel, Switzerland, 18 May 2004** One 15-minute infusion of the intravenous bisphosphonate zoledronic acid more rapidly reduced the biochemical markers of bone turnover in patients with Paget's disease than was seen in a head-to-head comparison with the oral treatment risedronate (95% vs. 75% response rate). These findings are according to data presented at the annual meeting of the World Congress on Osteoporosis (WCO) in Brazil.

The data, from the landmark HORIZON (Health Outcomes and Reduced Incidence with Zoledronic Acid ONce Yearly) Clinical Development Program, provide the basis for a marketing application recently submitted by Novartis Pharma AG to the European Agency for Evaluation of Medicinal Products (EMA) in the European Union, for the use of zoledronic acid as a treatment for Paget's disease. This is the first filing for the use of zoledronic acid in a benign metabolic bone disease.

"The availability of bisphosphonates in recent years has revolutionized the treatment of Paget's disease," said Paul D. Miller, MD, clinical professor of medicine and medical director of the Colorado Center for Bone Research, the lead investigator of the study. "These findings suggest that a single infusion of zoledronic acid may offer a fast, effective medication with very convenient dosing. This is extremely good news for patients."

The randomized, double-blind, active-controlled trial showed that in patients with Paget's disease, one 15-minute infusion of zoledronic acid 5 mg generated a therapeutic response in 95% of patients, compared with 75% of patients taking 30 mg/day of oral risedronate, for 60 days ( $P < 0.001$ ). At the six-month follow-up, serum alkaline phosphatase (SAP) levels, a key marker for bone turnover, were normal in 89% of zoledronic acid patients, compared with 56% of risedronate patients ( $P < 0.001$ ). The primary endpoint was therapeutic response at six months, defined as 75% reduction in, or normalization of, SAP, a standard measure of bone turnover.

**Additional information about Paget's disease**

Paget's disease of bone (also called osteitis deformans) is a painful and chronic disorder of bone metabolism, the biochemical process by which the skeletal system replenishes itself. In Paget's disease, accelerated breakdown and formation of bone produce new bone that is softer and weaker than normal. The disease causes pain, fractures and deformities that can seriously impede a patient's ability to partake in routine activities of daily living. Paget's disease can affect any part of the skeletal system, most commonly the skull, the spine and the bones of the arms, legs and pelvis. Complications of Paget's disease, the most common bone disease after osteoporosis, can include arthritis, bowing of the limbs and, if the disease affects the skull, hearing loss. Standard treatment for the disorder is primarily palliative (intended to reduce severity and ease symptoms) rather than curative.

"We are very pleased with the dramatic results we've seen so far with zoledronic acid," said Joerg Reinhardt, Head of Pharma Development, Novartis Pharma AG. "To be able to offer a convenient, single-dose treatment for potentially painful and debilitating metabolic bone diseases such as Paget's disease would represent a tremendous step forward for patients."

#### **About The HORIZON Clinical Development Program**

The HORIZON Clinical Development Program is the first to study a single-dose regimen for sustaining benefits of six months or longer in Paget's disease and once-yearly dosing for osteoporosis. The HORIZON program includes studies in postmenopausal osteoporosis for prevention of spine and hip fractures, the prevention of clinical fractures following a hip fracture in men and women, and the treatment of osteogenesis imperfecta in children. Worldwide, approximately 10,000 patients, in more than 200 trial centers, on four continents, are enrolled in the HORIZON program, one of the most comprehensive drug evaluation programs ever undertaken in the area of metabolic bone diseases.

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 "findings suggest," "may offer," "would represent," or similar expressions, or by or by express or implied statements regarding the potential for regulatory approvals to market zoledronic acid for treatment of Paget's disease or any other metabolic bone diseases in any market, or regarding potential future revenues from zoledronic acid from such indications. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with zoledronic acid to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that zoledronic acid will be approved for marketing in any jurisdiction for treatment of Paget's disease or any other metabolic bone disease, or that zoledronic acid will achieve any particular sales levels. Any such results can be affected by, among other things, uncertainties relating to product development, including the results of the ongoing HORIZON clinical trial and other such trials, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection, increased government pricing pressures and competition in general, as well as factors discussed in the Company's Form 20-F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis 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.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Sandoz strengthens global production network with three new facilities**

*New plants to open in Poland, India and Romania in May*

Vienna, May 18, 2004 Sandoz, the world's second largest supplier of generic medicines, is expanding its global production network with the opening of three new plants this month in Poland, India and Romania. The USD 80 million total investment will boost production capacity by three billion tablets and capsules, while creating approximately 500 jobs.

"Global presence in key markets is vital for competitiveness," says Christian Seiwald, CEO Sandoz. "These new plants put us in a better position to deliver high quality products promptly to our customers and increase our cost competitiveness."

All three plants will contribute substantially to meeting the increasing need for quality generic products and will support the continued growth of Sandoz.

The new production and logistics facility in **Strykow**, Poland, 20 km from Lodz, was built by Lek, the Slovenian Sandoz subsidiary. Opened on May 12, the plant is one of the largest investment projects of the pharmaceutical industry in the country, taking 1.5 years to complete. The Strykow plant includes an administration building, laboratories, production lines and storage centers. Focused on the production of oral solids, it is designed according to the latest GMP standards and guidelines and will provide products for the entire European market. The new facility is expected to create 150 new jobs. With the addition of the new plant, Lek will have a total of 500 employees in Poland.

The new Sandoz production plant in **Kalwe**, a suburb of Mumbai, was built in 16 months and will open on May 18. The plant will produce oral solids to supply world-wide markets. The new facility will be approved by both European and US public health authorities. With a staff of 200 working in the new plant, Sandoz will increase its total headcount to around 1,200 employees in India.

The **Targu Mures** production site in Romania, 360 km from the capital Bucharest, was built by Lek, the Slovenian Sandoz subsidiary. The construction took 1.5 years to complete and the plant will be inaugurated on May 25. Over 140 people in total will work in Targu Mures in all production and support activities supplying Antibiotics for the European and East European market. Including the new plant, Lek will have approximately 230 employees in Romania.

## Company Information

Sandoz, a Novartis company, is a world leader in generic pharmaceuticals and develops, manufactures and markets these medicines as well as pharmaceutical and biotechnological active ingredients. Decades of experience and profound know-how make Sandoz a renowned partner in the Franchises Pharmaceuticals, Biopharmaceuticals and Industrial Products. Altogether, Sandoz employs around 13,000 people worldwide and posted sales of USD 2.9 billion in 2003.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78,500 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

This release contains certain "forward-looking statements" relating to the Group's business, which can be identified by the use of forward-looking terminology such as "coming on stream", "will be", "to become", or similar expressions, or by express or implied discussions regarding strategies, plans and expectations. Such statements reflect the current plans or views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. Management's expectations could be affected by, among other things, competition in general, and other risks referred to in Novartis AG's Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Novartis marks 20 years of improving patients' lives with innovative treatments for transplantation**

*Past, present and future products span all therapeutic classes to address major unmet medical needs*

Basel, 14 May 2004 Demonstrating the strength of its 20 year commitment to improving transplant patients' lives, Novartis will present more than 50 abstracts on existing products and developmental compounds at the fifth annual American Transplant Congress (ATC) next week in Boston.

The data presented provide new insights into Novartis Transplantation's research strategies and the potential of Novartis' products to enhance therapeutic choices for transplant physicians and patients.

"Our goal is to provide treatment options that meet the needs of individual patients resulting in more successful transplants, better outcomes, safer therapies and longer, healthier lives for the transplant patients," said Tony Rosenberg, Head, Transplantation and Immunology Business Unit, Novartis Pharma AG. "For the transplant patient, it is no longer just a question of life, it is a question of living."

Novartis helped revolutionize the transplant field two decades ago by introducing Sandimmune® (cyclosporin). Novartis now provides physicians and patients with the largest selection of innovative transplant therapies of any pharmaceutical company, including the world's most widely prescribed anti-rejection product, Neoral® (cyclosporin for microemulsion), the recently approved *myfortic*® (enteric coated mycophenolate sodium) film tablets and Certican® (everolimus) which received European Mutual Recognition in 15 countries in December 2003.

"The introduction of cyclosporin 20 years ago revolutionized transplant patients' survival," said Russell H. Wiesner, M.D., President, United Network for Organ Sharing (UNOS). "As a result, many more people with organ failure became viable candidates for transplantation and there has been a dramatic increase in the number of organ transplants performed annually worldwide over the last two decades."

Today there are currently around 460,000 de novo and maintenance transplant patients alive worldwide. Novartis has continued to fuel advances in the science of transplantation with the introduction of a range of products including Simulect® (basiliximab).

Although transplantation has achieved great successes over the past 20 years, there are still advances that can be made to improve patients' quality of life. Novartis' aim is to enhance transplant patients' therapy with the introduction of innovative therapies.

"Every day I am both amazed and thankful for Novartis' ongoing research and introduction of new treatments that continue to improve the lives of transplant recipients," said Meghan Kelly, mother and living donor of liver transplant recipient, Thomas Kelly. "It has been nearly five years since my son's transplant surgery and thanks to novel therapies, not only does Thomas now live a normal life for a six year old, but sometimes, I almost forget that he needs to be taking medicine daily."

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

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Novartis confirms commitment to new markets of the European Union with major investment in Poland**

Stryków, 12 May 2004 Signalling its continued commitment to the emerging economies of the recently expanded European Union, Novartis AG today announced a EUR 70 million overall investment in a new generics production and logistics facility in Stryków, Poland.

Operated by Slovenia generics leader Lek, a new Sandoz company, the new facility is expected to create 150 new jobs in the Łódź region of Poland. The 25,000-square-meter complex will include an administration building, laboratories, production lines and storage centers.

"Today, we build on our 100 year presence in Poland with the opening of a major new facility. This better positions our generics business to participate in the exciting growth opportunities promised by the expansion of the European single market," said Paul Choffat, CEO of Novartis Consumer Health. "This world-class logistics and production site will produce high quality generic medicines that offer increased treatment options for physicians and patients throughout Poland and across Europe, complementing Novartis' broad portfolio of innovative, branded pharmaceuticals."

Initially focused on the production of oral solid formulations of generic medicines including Ketonal, Amlopin, Lovastatinum and Altacet the plant is expected to reach a production capacity of 1.5 billion tablets and capsules in the first year. Export production is estimated at 10% in the first year of operation, rising to as much as 20% thereafter.

In addition to the Stryków site, Novartis operates pharmaceutical and consumer health production sites in Rzeszów, Gorzów Wielkopolski and Pruszkow. In total, Novartis employs over 1500 people in Poland.

Sandoz, a Novartis company, is a world leader in generic pharmaceuticals and develops, manufactures and markets these medicines as well as pharmaceutical and biotechnological active ingredients. Decades of experience and profound know-how make Sandoz a renowned partner in the Franchises Pharmaceuticals, Biopharmaceuticals and Industrial Products. Altogether, Sandoz employs around 13,000 people worldwide and posted sales of USD 2.9 billion in 2003.

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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 "expected", "will include", "growth opportunities", "promised", "will produce", "offer increased treatment options", "is estimated", or similar expressions, or by express or implied discussions regarding the potential development and commercialization of new products or regarding potential future sales from any such products. 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 guarantee that the transactions that are the subject of this release will lead to the commercialization of any new products in any market, or that any such products will reach any particular sales levels. Any such commercialization or sales 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 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.

For further information please consult <http://www.novartis.com>.

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**INVESTOR RELATIONS RELEASE**

**Visudyne® launched in Japan for treatment of age-related macular degeneration**

Basel, Switzerland, 10 May 2004 Novartis Pharma AG announced that Visudyne® (verteporfin), currently the only treatment for some forms of "wet" Age-Related Macular Degeneration (AMD), was launched today in Japan. AMD is the leading cause of blindness in people over age 50. Visudyne was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) in October 2003 for the "wet" form of age-related macular degeneration with all types of subfoveal choroidal neovascularization (CNV).

"We are very pleased that we are able to bring this drug to the Japanese marketplace," said Flemming Ornskov, MD, President and Chief Executive Officer of Novartis Ophthalmics, the eye health unit of Novartis Pharma AG. "The progressive loss of central vision associated with AMD can have a devastating impact on a patient's quality of life. Without this treatment a person on average may be legally blind after just two years from diagnosis".

In Japan, the loss of vision is defined legally as the case when the corrected vision of both eyes are under 0.1 or when the corrected vision of first an eye is under 0.02 and with the vision of the second another eye being under 0.6.

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

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 and treatment in the initial stages of the disease are essential for patients to take the necessary steps that lead to diagnosis and early treatment to halt progression of AMD.

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.

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.

Visudyne is the only drug approved for the treatment of some forms of wet AMD, the leading cause of blindness in people over the age of 50, and has been used in more than 250,000 patients worldwide. Visudyne is commercially available in more than 70 countries mainly 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, U.S. 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.

The foregoing press release contains forward-looking statements that can be identified by terminology such as "able to bring", "may be", or similar expressions, or by express or implied discussions regarding potential future sales of Visudyne. 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 regarding potential future sales of Visudyne. In particular, management's expectations regarding commercialization of Visudyne could be affected by, among other things, additional analysis of Visudyne 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.

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.. Novartis Ophthalmics products are made in Switzerland, France, the United States 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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**INVESTOR RELATIONS RELEASE**

**Novartis files Femara applications in North America and Europe for indication as first ever post-tamoxifen treatment for early breast cancer**

*Submissions based on compelling data in postmenopausal women with early breast cancer; interim published data showed extended adjuvant treatment with Femara, following standard adjuvant (post-surgery) tamoxifen, cut risk of relapse nearly in half (43%)*

Basel, Switzerland, 10 May 2004 Novartis has submitted marketing applications in the United States, European Union and Switzerland for the use of Femara® (letrozole) in the extended adjuvant treatment of early breast cancer in postmenopausal women who have completed standard adjuvant (post-surgery) tamoxifen therapy and remained disease-free. These submissions mark the first time that data on a breast cancer therapy will be reviewed by health authorities for use of a medication following treatment with tamoxifen in the extended adjuvant setting.

The filings comprise results of the independent landmark MA-17 study, which was published expeditiously by the *New England Journal of Medicine* in the online edition on 9 October 2003. Updated results from the trial will be presented during the "Best of Oncology" session on Tuesday, 8 June, from 9:15-10:45 a.m. Central Time at the annual meeting of the American Society of Clinical Oncology (ASCO) in New Orleans, Louisiana, USA.

The term *extended adjuvant* describes the period following standard adjuvant treatment with tamoxifen. During this stage, the ongoing risk of relapse remains significant for patients regardless of whether cancer cells were detected in the lymph nodes (called *node positive*) or not (*node negative*) at the time of diagnosis of early breast cancer. There is currently no clinically proven post-tamoxifen therapy available for the approximately one million women worldwide who take tamoxifen in any given year. Upon completion of tamoxifen therapy, these women are potential candidates for treatment with Femara.

"These filings represent a very important opportunity for Novartis Oncology to help fill a critical gap in breast cancer treatment," said Diane Young, MD, vice president, global head, Clinical Development, Novartis Oncology. "This is an important milestone in the clinical development program for Femara, and we look forward to the results of the BIG 1-98 early adjuvant study, which compares Femara and tamoxifen during the first five years of treatment after surgery."

## Data

The filings were based on final data from an international, double-blind, randomized, multi-center study which included nearly 5,200 postmenopausal women with early breast cancer. The primary objective was to compare the disease-free survival of postmenopausal women taking Femara vs. placebo after approximately five years of post-surgery tamoxifen therapy. The interim published data showed, at a median interim follow-up of 28 months, that taking Femara after five years of adjuvant therapy with tamoxifen cut a woman's risk of recurrence nearly in half as compared with placebo (43% reduced risk of recurrence;  $P=0.00008$ ).

In addition, the estimated absolute improvement in disease free survival at four years was 6% for patients taking Femara compared with placebo (93% vs. 87%). 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.

The interim data from MA-17 were so compelling that last fall an Independent Data Safety Monitoring Committee and the investigators unblinded the study so patients taking placebo could be offered the opportunity to switch to Femara. These patients had been on placebo for up to five years (median 24 months) when they were offered to switch to Femara. They continue to be followed under an amended protocol. MA-17 is being coordinated by the National Cancer Institute of Canada Clinical Trials Group and supported by Novartis.

## Breast cancer recurrence

Approximately one-third of women with estrogen receptor-positive early breast cancer experience a recurrence. Over half of these recurrences occur more than five years after surgery, according to the Early Breast Cancer Trialists Group, Oxford, UK. Currently, it is estimated that more than one million women worldwide take adjuvant tamoxifen, which is currently the "gold standard" hormonal therapy for postmenopausal women with receptor-positive early breast cancer for the first five years after surgery. However, tamoxifen therapy has not been shown to provide additional benefit after five years and, traditionally, most women have not received treatment after completion of tamoxifen therapy. MA-17 is the first study that has provided clinical evidence to support use of medication, Femara, to reduce the risk of breast cancer recurrence during this extended adjuvant time period.

## Additional Femara adjuvant clinical trial

A Phase III early 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. More than 8,000 women have enrolled in this trial. Initial results from this study are expected by the end of the year.

## 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 80 countries worldwide. Not all indications are available in every country.

### Contraindications and adverse events

In the interim 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=0.01).

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 flashes (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.

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Additional information regarding Femara or Novartis Oncology can contact the websites [www.femara.com](http://www.femara.com) or [www.novartisoncology.com](http://www.novartisoncology.com) or additional media information can be found at [www.novartisoncologyvpo.com](http://www.novartisoncologyvpo.com).

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