

NOVARTIS AG  
Form 6-K  
January 07, 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 December 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:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes:  No:

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes:  No:

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Enclosures:

1.

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Novartis to acquire worldwide adult medical nutrition business of Mead Johnson & Company, strengthening its number two global position (Basel, December 16, 2003)

2. CIBA VISION launches virtual consultant web site (Atlanta, December 12, 2003)
  3. Sandoz acquires antibiotics production facility in Spain (Acquisition strengthens in-house production and adds freeze-drying technology (Vienna, 11 December 2003)
  4. New Data Show Higher Dosing of Gleevec Achieved Higher Response Rates in Patients with Newly Diagnosed Chronic Myeloid Leukemia (CML) (East Hanover, NJ, December 8, 2003)
  5. Post-tamoxifen Use Of Femara® In Postmenopausal Women With Early Breast Cancer Reduced Risk Of Recurrence By Nearly Half (43%) and Significantly Improved Disease-Free Survival, According to Data Presented at Major Medical Meeting (East Hanover, NJ, December 5, 2003)
  6. Certican® successfully completes European Mutual Recognition Procedure (Basel, December 3, 2003)
  7. GENEVA PHARMACEUTICALS, INC., RENAMED SANDOZ, INC. New Name Symbolizes Global Strength (Princeton, New Jersey, December 1, 2003)
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### Investor Relations Release

#### **Novartis to acquire worldwide adult medical nutrition business of Mead Johnson & Company, strengthening its number two global position**

*Transaction offers Novartis entry to U.S. retail medical nutrition channel and enhanced access to Japanese market*

*Established brands like Boost®, Isocal® and Ultracal® acquired to meet growing needs of outpatient and ageing population*

Basel, Switzerland, December 16, 2003 Novartis announced today its intention to acquire the brands, trademarks, patents and intellectual property assets of Mead Johnson & Company's global adult medical nutrition business in a US \$385 million cash transaction. Mead Johnson & Company, a subsidiary of Bristol-Myers Squibb Company, is a leader in sales and marketing of adult medical nutrition products.

Successful completion of the transaction will offer Novartis Medical Nutrition a strong presence in the fast-growing U.S. retail channel for medical nutrition products, expand its existing institutional medical nutrition business and enhance its access to the Japanese market. The

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acquisition will allow the business unit to further leverage its disease-specific brands consistent with its overall growth strategy.

"The acquisition of Mead Johnson & Company's adult medical nutrition business re-confirms our commitment to delivering high-quality products that help people maintain good health, recover from illnesses more quickly, and build the strength and vitality to combat disease," said Michel Gardet, Global Head of Novartis Medical Nutrition. "Enhancing our medical nutrition portfolio will allow us to better serve the needs of the growing outpatient and ageing populations."

The percentage of the U.S. population over 65 is expected to grow from 17% to 25% between 2005 and 2020.

Mead Johnson's principal adult medical nutrition brand Boost® is a complete oral nutritional liquid product designed to meet the caloric and nutritional requirements of the adult population. Other key products include Isocal®, an isotonic tube-feeding formula used to help patients manage inadequate voluntary oral intake due to conditions including cancer, anorexia and stroke; and Ultracal®, a general tube-feeding formula for patients who require dietary fiber to help normalize bowel functions.

Headquartered in Evansville, Indiana, USA, Mead Johnson & Company will continue to manufacture and supply the majority of the acquired products for Novartis on an ongoing basis. Sales of the acquired products exceeded US \$220 million in 2002.

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Novartis Medical Nutrition, with global sales of US \$711 million in 2002 (including Nutrition & Santé), offers a complete range of enteral (tube feeding) and oral nutrition products and devices tailored to the varying needs of patients and healthcare professionals. The product range encompasses supplements, which are taken orally, as well as other products administered through tube feeds and specific medical devices. Its key brands include Isosource®, Novasource®, Resource®, Impact® and Compat®.

Credit Suisse First Boston acted as the exclusive financial advisor to Novartis on this transaction.

### **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 "provides growth platform," "strengthens," "potential to expand," "is expected to," "upward trend," 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.

### **About Novartis**

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of US \$20.9 billion and a net income of USD 4.7 billion. The Group invested approximately US \$2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 77 200 people and operate in over 140 countries around the world. For further information, please consult <http://www.novartis.com>.

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**CIBA VISION LAUNCHES VIRTUAL CONSULTANT WEB SITE**

*Site Calculates Parameters and Makes Lens Recommendations for All Eye Care Professionals*

ATLANTA, Dec. 12, 2003 CIBA Vision today announced the launch of "Virtual Consultant", a web site at <http://virtualconsultant.cibavision.com> to assist eye care professionals in calculating initial base curve and trial contact lens powers for CIBA Vision lenses, as well as calculating for toric lens over-refractions. The site also assists in selecting the most appropriate contact lenses for patients and enables users to print the contact lens recommendations for retention in patient files.

"Virtual Consultant provides assistance to eye care professionals 24 hours a day, seven days a week," said Richard E. Weisbarth, vice president of Professional Services for CIBA Vision North America. "We developed this valuable resource to provide eye care professionals with the fitting assistance they need, when they need it making the fitting process as simple as possible."

Unlike other contact lens manufacturers' calculators, Virtual Consultant is available to all eye care professionals in North America. It can be accessed directly at <http://virtualconsultant.cibavision.com>, or through a link on [www.cibavision.com](http://www.cibavision.com).

With worldwide headquarters in Atlanta, CIBA Vision is a global leader in research, development and manufacturing of optical and ophthalmic products and services, including contact lenses, lens care products and ophthalmic surgical products. CIBA Vision products are available in more than 70 countries. For more information, visit the CIBA Vision web site at [www.cibavision.com](http://www.cibavision.com).

CIBA Vision is the eye care unit of Novartis AG (NYSE: NVS). Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately USD 2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 77,200 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**

**Sandoz acquires antibiotics production facility in Spain**

*Acquisition strengthens in-house production and adds freeze-drying technology*

Vienna, 11 December 2003 Sandoz, the generics business unit of Novartis, announced today that it has acquired the production plant of Amifarma S.L. in Palafolls, which is located north of Barcelona, Spain, for an undisclosed sum.

Amifarma whose product range is focused on sterile, injectable bulk antibiotics generated sales of EURO 23.5 million in 2002. Its 13 000<sup>m</sup> plant began operations in 1996 and is currently staffed by 41 employees, who will be integrated into the Spanish affiliate of Sandoz.

This deal follows a number of strategic acquisitions by Sandoz in recent years to complement its fast-growing generic pharmaceuticals business, the largest and most recent being the acquisition of Lek just over a year ago.

Christian Seiwald, CEO of Sandoz, commented: "The Palafolls plant is an important strategic fit in our operations. It offers us additional new technology and enhances our position in the niche segment of sterile penicillins, complementing our industry-leading range of anti-infectives. Amifarma has already been supplying some important active ingredients to Sandoz affiliates, so this acquisition also increases our level of vertical integration."

Heinrich Scherfler, Global Head of the Sandoz Industrial Products Franchise, added: "Our existing state-of-art plant in Les Franqueses, Spain, is already a leading center of excellence for Sandoz' production of oral semi-synthetic penicillins. Palafolls now provides us with freeze-drying-technology for antibiotics and complements our sterile production capacity."

As one of the world's leading manufacturers of antibiotics, Sandoz has a broad range of anti-infective comprising penicillins, cephalosporins, makrolides and combination products, such as the highly successful antibiotic AmoxC, a generic version of Augmentin<sup>1</sup>.

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Augmentin® is a registered trademark of GlaxoSmithKline

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. Long-standing experience and know-how make Sandoz a renowned partner in the Pharmaceuticals, Biopharmaceuticals and Industrial Product franchises. With approximately 11 500 employees worldwide, Sandoz posted sales of USD 1.8 billion in 2002.

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This release contains certain "forward-looking statements", relating to both the Novartis Group's and Sandoz' businesses, which can be identified by the use of forward-looking terminology such as "will" or similar expressions or by discussions of strategy, plans or intentions. Such statements reflect the current views of Novartis with respect to future events and are subject to certain risks, uncertainties and assumptions. These risks include uncertainties relating to production development, potential labor relations issues, unexpected regulatory delays or government regulation generally, and obtaining and protecting intellectual property, as well as factors discussed in the Form 20-F filed by Novartis 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. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of 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 78 200 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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### MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

#### **New Data Show Higher Dosing of Gleevec Achieved Higher Response Rates in Patients with Newly Diagnosed Chronic Myeloid Leukemia (CML)**

*Early Findings Among Clinical Research Presented at American Society of Hematology (ASH) Meeting; At 12 months, 92% of evaluable CML patients taking 800 mg Gleevec achieved a CCR compared to 72% taking the standard 400 mg*

East Hanover, NJ, December 8, 2003 New data demonstrated that at 12 months, newly diagnosed patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) taking 800 mg/day of Gleevec® (imatinib mesylate)\* achieved higher complete cytogenetic responses (CCR) compared to those taking the standard 400 mg/day dose. Significantly more patients in the higher dose group also achieved a molecular response compared to those in the standard dose group. These early data were presented this week at the annual meeting of the American Society of Hematology (ASH) in San Diego, California.

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Outside the U.S.: Glivec® (imatinib)

Researchers found that 53% of evaluable patients with newly diagnosed CML who were taking 800 mg of Gleevec achieved a CCR at three months compared to 37% of patients who were taking the standard dose. At 12 months, 92% of evaluable patients taking 800 mg achieved a CCR compared to 72% of those taking the standard dose. A CCR is the elimination of cells containing the Ph chromosome, the genetic abnormality that characterizes most cases of CML. CCR is a major goal of therapy.

"Previously published data of other therapies suggest that the earlier patients achieve a CCR, the better their prognosis," said Jorge Cortes, Associate Professor of Medicine and Deputy Chair, Department of Leukemia, The University of Texas, M.D. Anderson Cancer Center. "If confirmed, these early results may provide a new approach for initial treatment."

In addition to more rapid CCR, researchers found that more patients achieved a molecular response with 24% (15/62) patients achieving undetectable Bcr-Abl at the higher dose (800 mg/day) compared to 5% (2/43) patients taking the standard dose (400 mg/day). Molecular

response is a relatively new and more sensitive tool capable of detecting extremely minute quantities of residual leukemia cells in the body following treatment. Molecular response may prove a possible new benchmark for evaluating drug therapy effectiveness and prognosis.

### Study Details

In two consecutive trials in patients with previously untreated newly diagnosed Ph+ CML, researchers treated 167 patients with previously untreated CML in early chronic phase with Gleevec. One trial included 50 patients treated with the standard dose of Gleevec (400 mg/day). The other trial included 117 patients treated with a total daily dose of 800 mg. At 12 months, 105 patients were evaluable (43 at the 400 mg dose and 62 at the 800 mg dose).

The median follow-up for patients treated at the standard dose was 24 months while the median follow-up for patients treated at the 800 mg dose was 13 months. Although side effects were similar with the two dose schedules, myelosuppression was more common at the higher dose, with grade  $\geq 3$  anemia, neutropenia and thrombocytopenia occurring in 10%, 35%, and 25% of patients treated with 800 mg, respectively, versus 4%, 20% and 10% of patients treated with 400 mg, respectively. Generally, in most patients side effects such as neutropenia were transient and did not require permanent dose reduction below 600 mg. At 12 months, median actual dose for the group started at 800 mg was still 800 mg with 19% (15/79) patients requiring dose reduction to 400 or 300 mg of Gleevec.

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### About Gleevec

Gleevec is indicated for the treatment of newly diagnosed adult patients with Ph+ CML in chronic phase. Follow-up is limited. Gleevec is also indicated for the treatment of patients with Ph+ CML in blast crisis, in accelerated phase, or in chronic phase after failure of interferon-alpha therapy. Gleevec is also approved for the treatment of pediatric patients with Ph+ chronic phase CML whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy.

In February 2002, just nine months following the initial CML approval, Gleevec received FDA approval for the treatment of patients with Kit (CD 117) positive unresectable (inoperable) and/or metastatic malignant gastrointestinal stromal tumors (GISTs). The effectiveness of Gleevec in GIST is based on the objective response rate. In the pediatric indication, the original CML indication and in the GIST indication in adults, there are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

Gleevec is approved as Glivec® (imatinib) in the EU, Switzerland and other countries.

### Contraindications, Warnings and Adverse Events

The majority of CML patients who received Gleevec in clinical studies experienced adverse events, but they were usually mild or moderate. The most frequently reported adverse events (all grades) regardless of suspected relationship to treatment were superficial edema (53%-71%), nausea (43%-71%), diarrhea (30%-55%), muscle cramps (27%-55%), musculoskeletal pain (34%-46%), rash (32%-44%), and abdominal pain (23%-33%). In most cases, these events were managed without having to reduce the dose of Gleevec or interrupt treatment. Gleevec was discontinued because of adverse events in only 2% of patients in chronic phase, 3% in accelerated phase, and 5% in blast crisis.

Severe (NCI Grades  $^3/4$ ) neutropenia (2%-48%), thrombocytopenia (<1%-33%), hemorrhage (<1%-19%), fluid retention (including severe superficial edema) (<1%-12%), musculoskeletal pain (2%-9%), and hepatotoxicity (<1%-4%) were also reported among Gleevec recipients.

In the GIST trial that was the basis for GIST approval, drug was discontinued for adverse events in six patients (8%). In this clinical trial, the most common adverse events were edema, nausea, diarrhea, abdominal pain, muscle cramps, fatigue and rash. In this trial, seven patients (5%) were reported to have gastrointestinal bleeds and/or intratumoral bleeds. Gastrointestinal tumor sites may have been the source of GI bleeds.

Use of Gleevec is contraindicated in patients with hypersensitivity to imatinib or to any other component of Gleevec.

Women of childbearing potential should be advised to avoid becoming pregnant while taking Gleevec.

Gleevec should be taken with food and a large glass of water to minimize GI irritation.

Dose adjustments may be necessary due to hepatotoxicity, other nonhematologic adverse events, or hematologic adverse events.

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Gleevec is metabolized by the CYP3A4 isoenzyme and is an inhibitor of CYP3A4, CYP2D6, and CYP2C9. Please see full Prescribing Information for potential drug interactions.

Patients should be weighed and monitored regularly for signs and symptoms of edema, which can be serious or life threatening.

Numbers indicate the range in percentages in 4 studies among patients with CML in blast crisis, accelerated phase, and chronic phase.

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The foregoing release contains forward-looking statements that can be identified by terminology such as "new approach", "may provide," "greater," "faster," "more rapid," "suggest" or similar expressions, or by discussions regarding potential new indications for Gleevec, or regarding the long-term impact of a patient's use of Gleevec. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Gleevec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Gleevec will be approved for any additional indications in any market. Neither can there be any guarantee regarding the long-term impact of a patient's use of Gleevec. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Gleevec could be affected by, among other things, additional analysis of Gleevec 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 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.

### About Novartis

Novartis Oncology is a business unit within Novartis AG (NYSE: NVS), a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately USD 2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 77,200 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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Information about Gleevec is available at [www.gleevec.com](http://www.gleevec.com). Additional information is available on the Novartis Oncology Virtual Press Office, [www.novartisoncologyVPO.com](http://www.novartisoncologyVPO.com). The site features background information on Gleevec and other Novartis Oncology products.

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG****Post-tamoxifen Use Of Femara® In Postmenopausal Women With Early Breast Cancer Reduced Risk Of Recurrence By Nearly Half (43%) and Significantly Improved Disease-Free Survival, According to Data Presented at Major Medical Meeting**

*Extended adjuvant data presented at San Antonio Breast Cancer Symposium supported by new data on quality of life with Femara vs. placebo, from same clinical trial*

East Hanover, NJ, December 5, 2003 Extended adjuvant treatment with Femara® (letrozole tablets) in a group of postmenopausal women with early breast cancer who had completed five years of therapy with tamoxifen cut the risk of recurrence of early breast cancer nearly in half (43%), and newly analyzed data showed the quality of life for patients on Femara was generally comparable to that of patients taking placebo, according to data presented today at the San Antonio Breast Cancer Symposium. This independent, international study was coordinated by the National Cancer Institute of Canada Clinical Trials Group, Kingston, Ontario.

"Femara is the first therapy shown to reduce the risk of recurrence in postmenopausal breast cancer patients after five years of tamoxifen," said Diane Young, MD, vice president, global head, clinical development, Novartis Oncology. "These new data are encouraging because they suggest that in addition to the potential benefit of reduced risk of recurrence, Femara was seen to be well-tolerated and the safety profile was consistent with previous clinical trials without unduly compromising patient's quality of life."

Quality of life included patients' ability to engage in activities of everyday living, including work and recreation, subjective evaluation of mood and emotion and occurrence of adverse events as measured by the SF-36 Health Survey, a general health status questionnaire. SF-36 has been widely used both in well and chronic disease populations and is recognized to be reliable and valid. A Menopause-Specific Quality of Life Questionnaire also was included in the quality of life assessment.

**Study Highlights**

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

At a median follow-up of 2.4 years, the data in the Femara group showed a 43% reduction in risk of overall recurrence compared with placebo (P=0.00008) as well as a significant reduction (46%) in contralateral disease (cancer occurring in the other breast). The estimated absolute improvement in disease free survival at four years was 6% for postmenopausal patients taking Femara compared with placebo (93% Femara vs. 87% placebo). These numbers are nearly twice those the investigators anticipated when they designed the trial. The study was originally designed to show a 2.5% improvement in four-year disease free survival, from a baseline of 88% in the placebo arm. Disease free survival is defined as the time from randomization to the time of first recurrence of the primary disease in the breast (including contralateral breast), chest wall, nodal or metastatic sites.

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

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**Study Details**

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

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

The international study is being coordinated by the National Cancer Institute of Canada Clinical Trials Group in Kingston, Ontario. The interim data were published earlier this year in the November 6 issue of *The New England Journal of Medicine*.

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

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

### **About Femara**

Femara, a leading, once-a-day oral aromatase inhibitor, is indicated for first-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. Femara is also indicated for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy.

#### Femara Contraindications and Adverse Events

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

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

Femara is generally well tolerated and is contraindicated in patients with known hypersensitivity to Femara or any of its excipients. The most commonly reported adverse events for Femara vs. tamoxifen 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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The foregoing release contains forward-looking statements that can be identified by terminology such as "significant progress," "consistently demonstrated remarkable results," "compelling," "improved," "benefited significantly," "recommend," "may have substantial impact," "look forward to data," "help answer the question," or similar expressions, or by express or implied discussions regarding potential new indications for Femara or potential future sales of Femara, or regarding the long-term impact of a patient's use of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will be approved for any additional indications in any market. Nor can there be any guarantee regarding potential future sales of Femara. Neither can there be any guarantee regarding the long-term impact of a patient's use of Femara. In particular, management's expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

### **Patient Information**

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For more information on the results of this clinical trial, please visit the National Cancer Institute at [www.cancer.gov](http://www.cancer.gov) or call 1-800-4CANCER, or visit the Canadian Cancer Society at its website at [www.cancer.ca](http://www.cancer.ca), or information service toll-free number 1-888 939-3333.

Patients and physicians interested in more information regarding Femara or Novartis Oncology can contact the Novartis toll-free number 1-866-4Femara, or the websites [www.novartis.com](http://www.novartis.com), [www.us.femara.com](http://www.us.femara.com), or [www.novartisoncology.com](http://www.novartisoncology.com).

### About Novartis

Novartis Oncology is a business unit within Novartis AG (NYSE: NVS), a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately USD 2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 77,200 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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Additional information can be found at [www.us.femara.com](http://www.us.femara.com) or on the Novartis Oncology Virtual Press Office, [www.novartisoncologyVPO.com](http://www.novartisoncologyVPO.com). The site features background information on Novartis Oncology products.

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#### Investor Relations Release

### Certican® successfully completes European Mutual Recognition Procedure

*Certican first in its class to receive indication for heart as well as kidney transplant recipients*

Basel, December 3, 2003 Novartis announced today that it has successfully completed the European Mutual Recognition Procedure (MRP) in 15 countries for Certican® (everolimus) for the prevention of rejection episodes following heart or kidney transplantation. Certican will be

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

indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal or cardiac transplant. Certican should be used in combination with ciclosporin for microemulsion and corticosteroids. All countries involved in the MRP are expected to issue a marketing authorization in the coming months. Certican, a novel proliferation signal inhibitor, is the first drug in its class to receive the indication for heart as well as kidney transplant patients.

"Certican is a welcome addition to our established portfolio of marketed products that have enhanced the lives of transplant recipients," said Tony Rosenberg, Head, Transplantation and Immunology Business Unit, Novartis Pharma AG. "Certican could offer transplant patients and physicians a powerful tool to improve long-term survival through its ability to reduce the incidence and severity of the primary causes of rejection."

Certican is a novel proliferation signal inhibitor with immunosuppressant properties that targets primary causes of allograft dysfunction also known as chronic rejection of a transplanted organ), including acute rejection and vascular remodeling<sup>1,2,3</sup>. In addition, Certican is used with low dose ciclosporin.<sup>4</sup> Preventing allograft dysfunction is a major unmet medical need in transplantation.<sup>5</sup>

"The availability of Certican marks another step forward for individuals requiring transplantation," said Professor Mario Vigano, Professor of Cardiac Surgery, San Matteo Hospital, Pavia, Italy, and a lead investigator for Certican in heart transplant. "As each promising new agent becomes available, opportunities to improve short- and long-term survival after transplantation are renewed. We anticipate that Certican will contribute importantly to the well being of patients requiring this remarkable therapy."

The European countries' decision under the MRP is based on data from studies which comprised 634 heart transplant patients for 24 months and more than 1 700 kidney transplant patients for up to 36 months. Results demonstrated that Certican effectively prevented graft rejection when administered with Neoral® and corticosteroids.

At the completion of the MRP, the following 15 countries have endorsed the mutually agreed summary of product characteristics (SmPC): Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, and Sweden. Certican received its first approval from the Swedish Medical Products Agency in July 2003 for the prevention of rejection in heart and kidney transplant patients in combination with Neoral and corticosteroids. Sweden is the Reference Member State for the Mutual Recognition Procedure.

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

This release contains certain "forward-looking statements," relating to the Company's business, which can be identified by the use of forward-looking terminology such as "will be", "should be", "are expected", "could offer", "anticipate", "will contribute", or similar expressions, or by express or implied discussions regarding the potential futures sales and approvals 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 that may cause actual results with Certican to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Certican will reach any particular sales level. Any such commercialization can be affected by, among other things, uncertainties relating to 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, increased government price pressures, as well as factors discussed in the Company's Form 20-F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of 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 78 200 people and operate in over 140 countries around the world. For further information, please consult <http://www.novartis.com>

### 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® (ciclosporin for microemulsion) is one of the key treatments of immunosuppression in transplant patients, permitting long-term survival, but the risk of acute and chronic graft rejection

persists.

Certican is a proliferation signal inhibitor with immunosuppressant properties and will be available as an oral tablet and dispersible tablet formulations, to be used in combination with Neoral (ciclosporin for microemulsion) to suppress T-lymphocyte proliferation, and to be used with corticosteroids.

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

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**GENEVA PHARMACEUTICALS, INC., RENAMED SANDOZ, INC.**  
**New Name Symbolizes Global Strength**

PRINCETON, NEW JERSEY, December 1, 2003 Geneva Pharmaceuticals, Inc., a Novartis company and one of the leading Generic pharmaceutical companies in the U.S., announced it will be conducting its operations under the company name Sandoz Inc., effective Dec. 1, 2003. This company name change is part of a worldwide initiative by Novartis, one of the world's leading pharmaceutical companies, to unite its generics operations previously referred to as Novartis Generics under a single common name, Sandoz. The global launch of the Sandoz name took place May 21, 2003, in Vienna, Austria, the location of Sandoz Global Headquarters.

John Sedor, President and CEO of Sandoz, Inc., in the U.S., stated, "All of Novartis's generics companies sharing one common name will emphasize and strengthen our global network. We have the ability to obtain products more efficiently and leverage each other's strengths to best serve the needs of our customers, and ultimately our patients. Also, we're delighted to become Sandoz, a name with tremendous history and a solid reputation in the industry. It reinforces Novartis's commitment to the generics business."

Christian Seiwald, CEO of Sandoz GmbH, commented, "Over the last few years, Novartis Generics has grown extremely dynamically and has undertaken a series of strategic acquisitions. While we are currently the world's second-biggest generics group, we are not recognized as such due to the large number of different company names. The establishment of a uniform identity represents a milestone in our strategy for strengthening and harmonizing our international business."

In Seiwald's view, the Sandoz name reinforces the company's reputation for high quality and innovation, and provides the additional bonus of a company tradition going back more than a century. "We want Sandoz to become the undisputed No. 1 global name for generic pharmaceutical products," he said.

Sandoz, established in Basel, Switzerland, in 1886, was an international, branded pharmaceutical company up until the merger with Ciba Geigy in 1996, which formed Novartis. The renaming of Novartis Generics now marks the return of this time-honored name. 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 know-how make Sandoz a renowned partner in Pharmaceuticals, Biopharmaceuticals and Industrial Products. Altogether, Sandoz employs approximately 11,500 people worldwide and posted sales of USD 1.8 billion in 2002. More information on Sandoz can be found at <http://www.sandoz.com>.

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In the U.S., Sandoz, Inc., is one of the largest prescription generic pharmaceutical companies. The company produces more than 200 products each year, with an annual manufacturing capability exceeding 10 billion tablets and capsules. Sandoz products range across many therapeutic drug categories including anti-infectives, anti-arthritics, cardiovasculars, gastrointestinal agents and psychotherapeutics. More information about Sandoz U.S. operations can be found at <http://www.us.sandoz.com>.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately USD 2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 77,200 people and operate in more than 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 U.S. Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.*

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**SIGNATURES**

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: January 6, 2004

By:           /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: *Head Group Financial Reporting and Accounting*

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