

NOVARTIS AG  
Form 6-K  
July 02, 2003

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## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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### FORM 6-K

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

Report on Form 6-K for the month of June 2003

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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 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. Novartis Ophthalmics and Genentech announce development and commercialization agreement for age-related macular degeneration treatment, Lucentis (25 June 2003)
2. Results of LIS2T study indicate that Neoral® is associated with less diabetes and diarrhoea than tacrolimus in liver transplantation (23 June 2003)
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FDA approves Xolair®, biotechnology breakthrough for asthma (23 June 2003)

4. New data confirm that Prexige® (lumiracoxib) is effective in relieving symptoms of osteoarthritis (20 June 2003)
5. NICE issues preliminary recommendation for Glivec® in England and Wales as first-line drug therapy for patients with chronic myeloid leukemia (18 June 2003)
6. Recipients of the 5<sup>th</sup> Annual Novartis Award in Diabetes honored today (16 June 2003)
7. FDA approves Stalevo® for treatment of Parkinson's disease (13 June 2003)
8. EMEA updates Zometa® label to include longer-term efficacy data on prevention of bone complications in advanced cancers (12 June 2003)
9. US International Trade Commission determines legal dispute between GSK and Novartis should go to trial (11 June 2003)
10. Elidel® cream provides fast relief for infants with atopic dermatitis (10 June 2003)
11. First and largest statin trial in renal transplant patients demonstrates that Lescol® reduces cardiac death and heart attack (3 June 2003)
12. Transplanted kidneys from living donors survive longer using immunosuppression with Neoral® compared with tacrolimus (3 June 2003)
13. Giving the right nutrients before surgery cuts postoperative infections and lowers hospital costs (3 June 2003)
14. Early data from 6 600 patients in Glivec® Expanded Access Program consistent with published survival data for Ph+ chronic myeloid leukemia patient (2 June 2003)
15. Study shows longer pre-operative treatment with Femara® significantly increases chance of breast-conserving surgery in post-menopausal women with locally advanced breast cancer (2 June 2003)
16. Novartis Medical Nutrition acquires Semper Clinical Nutrition, a leader in medical nutrition in the Nordic region (Stockholm, June 2, 2003)

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**Investor Relations Release**

**Novartis Ophthalmics and Genentech announce development and commercialization agreement for age-related macular degeneration treatment, Lucentis**

Basel, 25 June 2003 Novartis Ophthalmics, the eye health unit of Novartis AG and Genentech, Inc. today announced that they have entered into an agreement under which Novartis Ophthalmics will receive an exclusive license to develop and market Lucentis (ranibizumab), formerly known as rhuFab V2, an anti-VEGF (vascular endothelial growth factor) antibody fragment, outside of North America for indications related to diseases of the eye. Lucentis is currently in Phase III clinical trials for the treatment of the wet form of age-related macular degeneration (AMD) in the United States.

Under the terms of the agreement, Genentech and Novartis will share certain global development costs. Genentech will receive an upfront fee, payments for achievement of clinical development milestones, and royalties on net sales of Lucentis products outside North America. Genentech will retain marketing rights for Lucentis in North America (United States, Canada and Mexico). Novartis Ophthalmics will receive exclusive commercialization rights for the rest of the world.

"This is a landmark accomplishment in our continued commitment as leaders in the development of drug therapies for diseases affecting the back of the eye. We are excited to have this opportunity to further strengthen our portfolio with another innovative product for AMD," said Flemming Ornskov, MD, MPH, Head of Novartis Ophthalmics. "Lucentis will be a strong addition to our ophthalmology franchise, which includes Visudyne® (verteporfin), the only approved drug treatment for a prevalent form of this disease."

"This strategic collaboration provides Genentech with a strong development and marketing collaborator for Lucentis outside of North America," said Joseph McCracken, D.V.M, Vice President, Business and Commercial Development. "Novartis Ophthalmics' experience and proven success in the retinal disease market will allow Lucentis, if approved, to compete effectively on a global basis."

**About Lucentis**

Lucentis (ranibizumab) is a humanized, therapeutic antibody fragment developed at Genentech to bind and inhibit VEGF, a protein that plays a critical role in angiogenesis (the formation of new blood vessels). Lucentis is designed to block new blood vessel growth and leakiness, which are thought to lead to wet AMD disease progression.

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On October 1, 2002, Genentech announced positive preliminary data from a Phase Ib/II randomized, single-agent study with Lucentis for patients with the wet form of AMD. In that study, sixty-four patients were enrolled in a single-agent, multi-center trial. Patients were treated in one eye every four weeks for four doses (either 300 or 500 micrograms) of Lucentis (n=53) or were treated with standard of care (no Lucentis) (n=11). Three different groups of subjects were enrolled in the study based on disease pattern and prior treatment: minimally classic, predominantly classic (both refer to particular patterns of leakiness and lesion characteristics seen on an angiogram), and patients previously treated with photodynamic therapy (PDT).

Patients were monitored for safety and visual acuity. Visual acuity is defined as the total number of letters read correctly on the Early Diabetic Retinopathy Study [ETDRS] chart. Of the 53 patients treated with Lucentis, 50 patients (94 percent) had stable or improved vision compared with the baseline, of which 14 patients (26 percent) improved 15 letters or more on the ETDRS chart, and 36 patients (68 percent) had stable vision at day 98. Stable vision is defined as losing or gaining fewer than 15 letters on the ETDRS chart compared with the baseline.

On average, patients treated with Lucentis gained 9.0 letters at day 98 compared to patients treated with standard of care who lost 4.9 letters. The most common side effects from treatment with Lucentis were mild transient, reversible inflammation.

Based on this data, Genentech initiated a Phase III study in minimally classic and occult AMD in March 2003. Genentech this month began enrolling patients in a Phase III study in predominantly classic AMD.

## About AMD

AMD (age-related macular degeneration) is a major cause of painless, central visual loss and is the leading cause of blindness for 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.

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.

The foregoing release contains "forward-looking statements" that can be identified by forward looking terminology such as "will," "if approved," or similar expressions, or by express or implied discussions regarding the potential that Lucentis will be approved for marketing, or regarding potential revenues from Lucentis. Such statements reflect the current views of Novartis with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Lucentis will be approved for sale in any market, or regarding potential revenues from Lucentis. In particular, management's expectations could be affected by, among other things, new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government pricing pressures; and other risks and factors referred to in Novartis' 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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## About Novartis

With its registered office in Hettlingen, Switzerland, Novartis Ophthalmics is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of age-related macular degeneration, eye inflammation, glaucoma, ocular allergies and other diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. The North American headquarters is based in Atlanta, Georgia. Novartis Ophthalmics products are made in Switzerland, France and Canada. For more information, visit [www.novartisophthalmics.com](http://www.novartisophthalmics.com) or [www.novartisophthalmics.com/us](http://www.novartisophthalmics.com/us).

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>.

## About Genentech

Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes biotherapeutics for significant unmet medical needs. Sixteen of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes eleven biotechnology products in the United States. The company has headquarters in South San Francisco, California and is traded on the New York Stock Exchange under the symbol DNA. For press releases and additional information about the company, please visit <http://www.gene.com>.

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Results of LIS2T study indicate that Neoral® is associated with less diabetes and diarrhoea than tacrolimus in liver transplantation**

*New study data found that liver transplant patients receiving Neoral (cyclosporin for microemulsion) and managed by C<sub>2</sub> monitoring experience significantly less diabetes and diarrhoea compared to those given tacrolimus.*

Basel, 23 June 2003 Neoral® is as effective as tacrolimus in preventing acute rejection in liver transplant patients whilst also being better tolerated according to the 6 month analysis of the LIS2T study presented today at the annual International Liver Transplant Society (ILTS) meeting in Barcelona.<sup>1</sup> The study is the first ever multi-centre head-to-head comparison of the efficacy and tolerability of Neoral versus tacrolimus, where Neoral was monitored by C<sub>2</sub> blood levels. Previous studies have compared Neoral and tacrolimus based on trough monitoring (C<sub>0</sub>), however the benefits of Neoral C<sub>2</sub> monitoring have since been recognised.<sup>2</sup>

The analysis of the randomised, multi-centre study assessed 499 patients up until six months following their transplant and compared the efficacy and tolerability of Neoral using C<sub>2</sub> monitoring versus tacrolimus, in combination with steroids or steroids and azathioprine.

The results showed that the rates of acute liver rejection for Neoral and tacrolimus were similar, as were the incidences of graft loss and death. However, the study found that significantly more patients treated with tacrolimus suffered from diabetes and diarrhoea following their transplant. Specifically, the results showed that:

Significantly more patients treated with tacrolimus suffered from new-onset diabetes following transplantation compared to patients treated with Neoral (14% versus 7% respectively, p<0.05).

Significantly more patients treated with tacrolimus suffered from diarrhoea compared to patients treated with Neoral (28% versus 14% respectively, p<0.001).

There were no significant differences in rates of acute graft rejection (29% in the Neoral group versus 25% in the tacrolimus group).

There were no significant differences in the incidence of graft loss or death (11% in patients receiving Neoral versus 12% in patients receiving tacrolimus).

Professor Federico Villamil, Medical Director of the Liver Unit at Favaloro Foundation and Professor of Medicine at Favaloro University (Buenos Aires, Argentina) who presented the results today commented: "The important result to note is that Neoral and tacrolimus have comparable efficacy and that there is a difference in tolerability patients receiving Neoral experienced significantly less diabetes and diarrhoea compared to those receiving tacrolimus. Diabetes increases the patient's risk of organ failure, the long term risk of cardiovascular disease and finally the risk of death. Minimising the risk of diabetes in transplant patients is a key challenge facing physicians today."

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A total of 499 patients were recruited into the study from 17 countries. Patients will be followed up until one year after transplantation. These results follow an independent analysis presented earlier this month at the American Transplant Congress in Washington which showed that the long-term chances of survival of a transplant kidney from a living donor are significantly greater with immunosuppressive therapy based on Neoral than with therapy based on tacrolimus.<sup>3</sup>

Neoral is a cornerstone of immunosuppressive therapy for the majority of transplant patients, with one of the longest records of proven clinical experience. Neoral C<sub>2</sub> monitoring involves making Neoral dose adjustments based on the measurement of the concentration of cyclosporine in a patient's blood two hours (C<sub>2</sub>) after the dose. This allows for more precise dosing of Neoral in individual patients. Patient

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management by Neoral C<sub>2</sub> has been demonstrated to improve the outcome of transplantation with Neoral when compared to the traditional C<sub>0</sub> monitoring, including reducing significantly the incidence of moderate and severe rejection episodes in liver transplantation.<sup>2</sup>

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 "long-term", "will be", or similar expressions, or by express or implied discussions regarding potential future sales of Neoral. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There can be no guarantees that Neoral will reach any particular sales levels. Any results expressed or implied by such forward-looking statements 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, competition in general, increased government pricing pressures, as well as factors discussed in the Company's Form 20-F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of 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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**For an electronic and downloadable version of this press release**, please visit the transplantation media resource site [www.transplantsquare.com](http://www.transplantsquare.com).

### References:

1. F Villamil, B G Ericzon, A Risaliti, S Munn, G Cantisani, R Jones, M Rossi, G Klintmalm and G Levy. Efficacy and safety of cyclosporine microemulsion with C<sub>2</sub> monitoring versus tacrolimus in de novo liver transplant recipients. Presented at 2003 International Liver Transplant Society Meeting, Barcelona.
2. Levy GA et al. Improved clinical outcomes for liver transplant recipients using cyclosporine monitoring based on 2-hr post-dose levels (C<sub>2</sub>). *Transplantation* 2002; 73: 953-959.
3. Bunnapradist S, Daswani A, Takemoto SK. Renal Allograft Outcomes According To Initial Immunosuppressive Regimen: UNOS Renal Transplant Registry Data 1995-2000. Presented At 2003 American Transplant Congress, Washington DC.

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### Investor Relations Release

**FDA approves Xolair®, biotechnology breakthrough for asthma**

*First humanized antibody for asthma targets IgE, an underlying cause of the disease*

Basel, 23 June 2003 Novartis announced today that the novel IgE-blocker Xolair® (Omalizumab) for Subcutaneous Use has been approved by the US Food and Drug Administration (FDA) for the treatment of moderate-to-severe persistent asthma in adults and adolescents. Xolair is the first humanized therapeutic antibody for the treatment of asthma and the first approved therapy designed to target the antibody IgE, a key underlying cause of the symptoms of asthma that has an allergic component. Xolair is expected to be available in the US by July 2003.

Xolair is indicated for adults and adolescents (12 years of age and above) with moderate-to-severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions.

"We are delighted by this decision, which marks an important breakthrough for patients who are unable to control their asthma despite the wide range of therapies currently available," said Thomas Ebeling, Chief Executive Officer, Novartis Pharma AG. "Novartis and its collaborators are proud to have developed this innovative approach to tackling the growing problem of asthma, and we welcome the FDA's approval which allows us to turn this exciting scientific concept into a therapeutic reality for the benefit of patients and their families."

According to the National Institutes of Health, direct and indirect financial costs for all forms of asthma in the US totaled USD 14 billion in 1998. In addition, asthma leads to at least two million emergency room visits and more than 5000 deaths in the United States each year, according to the Center for Disease Control and Prevention's National Center for Health Statistics.

Xolair is being jointly developed under an agreement among Novartis Pharma AG, Genentech, Inc. and Tanox, Inc., and will be co-marketed in the United States by Genentech and Novartis Pharmaceuticals Corporation. In addition to approval in the United States, Xolair has also received marketing license from health authorities in Australia.

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**Clinical Study results**

The companies' data submission to the FDA included two 52-week pivotal Phase III clinical trials with 1071 asthma patients, 12-76 years of age, as well as data from several supportive safety and efficacy studies, including the 1899-patient ALTO safety study. The pivotal trials were designed to study a reduction in asthma exacerbations. The co-primary endpoint of each study was the number of asthma exacerbations per patient during the stable-steroid phase and the steroid-reduction phase. Patients were randomized to receive subcutaneous Xolair or placebo every two or four weeks. Doses were determined based on patients' body weight and IgE level. Inhaled corticosteroid doses were kept stable over the initial 16 weeks of treatment (stable-steroid phase) and tapered during a further 12-week treatment period (steroid-reduction phase).

When used as an add-on therapy to inhaled corticosteroids, in both pivotal clinical trials, Xolair reduced mean asthma exacerbations ("asthma attacks") per patient by 33%-75% during the stable-steroid phase and 33%-50% during the steroid-reduction phase. Reduction in asthma exacerbations was confirmed by improvements in other measures of asthma control including asthma symptom scores such as nocturnal awakenings and daytime asthma symptoms.

**Safety Information**

Xolair has not been shown to alleviate asthma exacerbations acutely and should not be used for the treatment of acute bronchospasm or status asthmaticus. Xolair should not be abruptly substituted for systemic or inhaled corticosteroids. Decreases in corticosteroids should be performed only under the direct supervision of a physician and may need to be reduced gradually.

The most serious adverse reactions occurring in clinical studies with Xolair are malignancies (0.5% in Xolair vs 0.2% in placebo) and anaphylaxis (<0.1% in Xolair). The difference in malignancy between the Xolair and placebo arms was not statistically significant. Xolair treatment is generally well tolerated. The most frequent adverse events included injection site reactions (45%), viral infections (23%), upper respiratory tract infections (20%), sinusitis (16%), headache (15%), and pharyngitis (11%). These events were observed at similar rates in Xolair-treated patients and control patients.

## About IgE and the Allergic Cascade

Asthma with an allergic component is a chronic inflammatory disorder of the airways, in which exposure to an aero-allergen triggers an allergic cascade that may result in airway inflammation and obstruction. In some patients, when allergens enter the body, IgE antibodies are produced and circulate in the blood. IgE circulating in the blood binds to mast cells, which contain the inflammatory chemicals (histamine, leukotrienes, others). Upon exposure to an allergen, IgE on the mast cell cross-links and triggers mast cells to release these chemicals. This chemical release triggers the inflammation, bronchial constriction and coughing associated with asthma. Xolair is designed to bind to the circulating IgE antibodies in the blood, decreasing the amount of IgE antibodies available to bind mast cells. With Xolair, fewer IgE antibodies can bind to mast cells, making IgE cross-linking less likely and inhibiting the mast cell's release of those chemicals that can lead to the symptoms of asthma.

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### Investor Relations Release

#### **New data confirm that Prexige® (lumiracoxib) is effective in relieving symptoms of osteoarthritis**

Basel, Switzerland, 20 June 2003 Data from key clinical Phase III studies presented for the first time at EULAR, the European League Against Rheumatism annual congress in Lisbon, demonstrate that Prexige® (lumiracoxib), a novel COX-2 selective inhibitor, provides effective relief of the symptoms of osteoarthritis (OA).



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Commenting on the trial data presented at EULAR, Dr Joerg Reinhardt, Head of Development, Novartis Pharma AG, said: "This body of data confirms that Prexige is an efficacious COX-2 selective inhibitor which could offer substantial benefit to patients with osteoarthritis."

The data presented include results from a 13-week pivotal study in OA that evaluated Prexige at 200mg and 400mg given once daily (od) compared with placebo and a 200mg single daily dose of celecoxib. Using Visual Analogue Scale (VAS) and the Western Ontario McMaster Universities osteoarthritis index (WOMAC) disease scores, the investigators, Fleischmann *et al.*, demonstrated that Prexige was significantly ( $p<0.001$ ) more effective in reducing OA pain intensity and improving functional status compared with placebo at end of study treatment. Furthermore, Prexige was as effective as celecoxib in terms of all primary efficacy assessments after 13 weeks (study duration) of treatment.

A further study by Schell *et al.* was presented which showed, for the first time, the long-term efficacy in patients with OA receiving Prexige at 200mg or 400mg od compared with celecoxib 200mg od for up to one year. Both doses of Prexige provided sustained long-term pain relief and maintained improvements in functional status in patients with OA of the knee. Prexige was as effective as celecoxib in terms of pain relief and improved functional status.

In a model conducted over 4 weeks of treatment, Benevolenskaya *et al.* showed that Prexige 100mg od was effective in reducing pain in patients with OA of the hip or knee, with the estimated treatment difference (VAS) of 8.41mm ( $p=0.003$ ). Prexige 100mg od significantly improved disease status, as assessed by the patient's and physician's global assessment of disease activity, with treatment differences of 8.81mm ( $p=0.001$ ) and 7.98mm ( $p=0.002$ ) respectively.

Additional benefits of Prexige were demonstrated through a one week study by Wittenberg *et al.*, who found that OA patients experienced effective relief of pain as little as three hours after taking Prexige ( $p=0.03$ ). The investigators found an overall adverse event profile similar to placebo and celecoxib. Prexige was significantly superior to placebo for overall pain relief throughout the study at both morning and evening assessments, with 13.9% of patients on lumiracoxib reporting complete pain relief at the study end, compared with 5.3% on placebo.

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COX-2 selective inhibitors selectively block the inflammation-producing COX-2 specific enzyme that is produced in arthritic joints, and unlike traditional NSAIDs, do not affect the COX-1 enzyme, which is important for protecting against gastrointestinal problems. Prexige is being evaluated for the treatment of arthritis and acute pain.

OA is the most common form of arthritis and is a significant burden for patients around the world. It is characterized by the breakdown of cartilage in joints, causing affected bones to rub against each other and leading to inflammation, pain and loss of movement. It is estimated that more than 25 million Europeans and 20.7 million Americans are affected by OA. Globally, it accounts for half of all chronic conditions in those age 65 and older.

The foregoing press release contains forward-looking statements that can be identified by express or implied statements regarding future clinical trial results regarding the safety or efficacy of Prexige, the potential for regulatory approvals to market Prexige, or potential future revenues from Prexige. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that other ongoing clinical trials, including the ongoing TARGET trial, will have the same results as the clinical trials described above. Nor can there be any guarantee that the clinical trials described above will result in the commercialisation of Prexige in any market. Neither can there be any guarantee regarding the potential future sales of Prexige, if it is approved. In particular, the fact that Prexige was shown to have similar safety and efficacy profiles as celecoxib does not mean that, if approved, Prexige sales would reach the same sales levels as celecoxib. Any such results can be affected by, amongst other things, uncertainties relating to product development, including the results of other clinical trials, including the ongoing TARGET trial and other 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 Novartis AG's Form 20-F filed 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 described herein as anticipated, believed, estimated or expected.

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1 Fleischmann *et al.*, A prospective randomized 13-week study evaluating the efficacy of lumiracoxib in patients with osteoarthritis of the knee (Study 109), EULAR 2003 Abstract Number FRI0233.

2 Schell *et al.*, Long-term efficacy and tolerability of lumiracoxib in patients with osteoarthritis of the knee (Study 112E), EULAR 2003 Abstract Number FRI0224.

3 Benevolenskaya *et al.*, Lumiracoxib is effective in relieving symptoms of osteoarthritis of the hip or knee after 4 weeks of treatment: results from a randomized placebo-controlled trial (Study 2316), EULAR 2003 Abstract Number FRI0246.

4 Wittenberg *et al.*, Prospective, randomized study on the first-dose analgesic effect of lumiracoxib in osteoarthritis of the knee (Study 2301), EULAR 2003 Abstract Number FRI0229.

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**NICE issues preliminary recommendation for Glivec® in England and Wales as first-line drug therapy for patients with chronic myeloid leukemia**

Basel, Switzerland, 18 June 2003 The National Institute for Clinical Excellence (NICE) has issued a preliminary recommendation that the Novartis drug Glivec® (imatinib)\* should be used for first-line treatment of patients newly diagnosed with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in the chronic phase. Glivec received a licence in the UK as part of the centralized EU license to treat newly diagnosed (Ph+) CML patients on 19 December 2002.

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

The final decision from the Institute is expected in July of this year. If the preliminary recommendation is confirmed, newly diagnosed chronic phase Ph+ CML patients in England and Wales will have access to Glivec treatment under the NHS as their first drug treatment option. Under current NICE guidance, Glivec is recommended for Ph+ CML patients in the blast crisis, accelerated phase or in chronic phase after failure or intolerance of interferon-alpha therapy. For people in chronic-phase CML currently receiving interferon-alpha (IFN) as first-line treatment, the choice of whether to change to Glivec should be based upon the response of the disease to current treatment and by the tolerance of the patient to IFN. This decision should be made after informed discussion between the patient and the responsible clinician.

Worldwide, CML has an incidence of one-to-two cases per 100 000 population per year and is responsible for 15 to 20% of all adult cases of leukemia. In England and Wales, approximately 2660 people have CML each year. The annual case rates are 1.0 per 100 000 men and 0.8 per 100 000 women, according to NICE.

**About Glivec**

Glivec is indicated for the treatment of newly diagnosed adult and pediatric patients with Ph+ CML in the EU, Switzerland, and a number of other markets. Glivec is approved in the U.S. for newly diagnosed adult patients with Ph+ chronic phase CML and pediatric patients with Ph+ chronic phase CML whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy. In addition, Glivec is already approved in over 80 countries for the treatment of adult patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.

Glivec is also approved in the EU, U.S., and more than 45 other countries for the treatment of patients with Kit (CD 117)-positive unresectable (inoperable) and/or metastatic malignant GISTs.

### Contraindications and Adverse Events

In the first-line International Randomized Study of Interferon vs. STI-571 (IRIS), the safety profile with Glivec was similar to that of previous Phase II studies in other CML patients. The majority of patients treated with Glivec experienced adverse events at some time. Most events were of mild to moderate grade and treatment was discontinued for adverse events only in 2% of patients in chronic phase, 3% in accelerated phase and 5% in blast crisis. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, as well as neutropenia and thrombocytopenia.

The most common undesirable effects experienced during Glivec treatment in GIST are: headache, nausea, vomiting, diarrhea, dyspepsia, myalgia, muscle spasm and cramps, joint swelling, dermatitis, eczema, rash, edema, fluid retention, neutropenia, thrombocytopenia or anemia.

Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

The foregoing release contains forward-looking statements that can be identified by terminology such as "preliminary recommendation," "should be used," "is expected", "if...will," or similar expressions, or by express or implied discussions regarding potential new indications for Glivec, or regarding potential future revenue from Glivec. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Glivec will be approved for any additional indications in any market. Neither can there be any guarantee regarding revenues from Glivec. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding Glivec could be affected by, among other things, additional analysis of Glivec clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected.

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Additional information on Novartis Oncology and Glivec can be found at [www.novartisoncology.com](http://www.novartisoncology.com) or [www.glivec.com](http://www.glivec.com). Additional media information can be found at [www.novartisoncologyvpo.com](http://www.novartisoncologyvpo.com).

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Recipients of the 5<sup>th</sup> Annual Novartis Award in Diabetes honored today**

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

*Judging panel continues to praise "outstanding" quality of nominations received*

Basel, 16 June 2003 Novartis honors the recipients of the 2003 Novartis Award in Diabetes. Four awards will be given today to clinical investigators judged to have made exceptional contributions to the field of diabetes. This year's Award recipients are Professor Jørn Nerup, Professor Ralph DeFronzo, Professor Andrew Hattersley and Dr. Lloyd Aiello.

The selection panel, comprised of independent internationally-recognized diabetes experts, selected two recipients in each of the categories: Long-Standing Achievement and Young Investigator.

Professor Eberhard Standl, Chair of the selection panel, said "We were again extremely impressed by the quality of the nominations this year. The recipients have conducted outstanding research, crucial to advancing our knowledge of diabetes. Their contributions have already had and will have a major impact on diabetes treatment and on the life of millions of people around the world who are affected by diabetes."

The Long-Standing Achievement Awards will be presented to Professor Jørn Nerup of Denmark and Professor Ralph A. DeFronzo of the USA for their exceptional and sustained achievements in clinical research, education and clinical practice.

Professor Nerup is Chief Physician at Steno Diabetes Center, Gentofte, Denmark and adjunct Professor at the University of Copenhagen School of Medicine. As the leader of a laboratory dedicated to the study of Type 1 diabetes pathogenesis he has been the mentor of numerous young researchers and clinicians. Professor Nerup obtained the first experimental and clinical demonstration that type 1 diabetes is an autoimmune disease and discovered its association with HLA as a genetic and pathogenetic marker of distinction from Type 2 diabetes and has published over 400 scientific articles. He is also a dedicated physician, spending half his time caring for patients.

Professor DeFronzo is Professor of Medicine and the Chief, Diabetes Division, at the University of Texas Health Science Center at San Antonio, and Deputy Director, Texas Diabetes Institute, USA. He has published over 400 scientific articles and is acknowledged for his dedication to the training of over 150 young clinical investigators. Professor DeFronzo has made major contributions to the development of novel technologies that have greatly advanced knowledge about the pathogenesis and metabolic abnormalities that characterize type 2 diabetes mellitus, the insulin resistance syndrome, obesity, hypertension, dyslipidemia and others.

The Young Investigator Award recognizes innovative patient-oriented research in the fields of physiology, path physiology or epidemiology of diabetes and its complications. Awards will be presented to Professor Andrew T. Hattersley of the UK and Dr. Lloyd P. Aiello of the USA.

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Professor Hattersley is Professor in Molecular Medicine and a Consultant Diabetologist at the Peninsula Medical School in Exeter, UK. He is an international leader in the field of the genetics of diabetes, particularly the monogenic form of diabetes, maturity-onset diabetes of the young (MODY) publishing over 140 scientific papers. Professor Hattersley's work has been said to go "from patients to genes and back again". He has defined genes that cause diabetes and is now pioneering using molecular genetic information in the diabetic clinic to improve the diagnosis and treatment of patients.

Dr. Aiello is the Associate Director of the Beetham Eye Institute at Joslin Diabetes Centre, one of the leading diabetes ophthalmologic research and clinical centers in the world. He published the first extensive study showing that the level of vascular endothelial growth factor (VEGF) correlated with the severity of diabetic retinopathy. Dr. Aiello has published numerous papers in top rated journals, including The New England Journal of Medicine, Proceedings of the National Academy of Science, Journal of Clinical Investigation, Diabetes Care and many others.

"We, at Novartis, honor this year's recipients for their personal and professional commitment to diabetes," said Dr. James Shannon, Global Head of Clinical Development and Medical Affairs from Novartis. "Now in its 5th year, we hope that the Novartis Award in Diabetes will continue to inspire researchers from around the world to strive for the highest standards in diabetes treatment and clinical research."

Award Recipients will be presented with their Awards and \$25,000 US each by Panel members during a Gala Presentation Dinner to be held tonight at the Musee Conti, New Orleans.

**Novartis Commitment to Diabetes**

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

This international award is one of many activities that Novartis is supporting to help increase awareness of and urgency for innovation in diabetes research, education and clinical practice. Novartis is constantly exploring new approaches for the treatment of type 2 diabetes, including the novel insulin secretion agent, Starlix® (nateglinide), which has been approved in many countries around the world. Nateglinide is licensed to Novartis Pharma AG from Ajinomoto Co., Inc.

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### Investor Relations Release

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

##### *New drug reduces signs and symptoms of disease*

Basel, 13 June 2003 Novartis announced today that the U.S. Food and Drug Administration (FDA) has approved Stalevo (carbidopa, levodopa and entacapone) tablets, for the treatment of patients with idiopathic Parkinson's disease (PD) who experience signs and symptoms of end-of-dose "wearing-off."

Stalevo contains levodopa, the most widely used agent for Parkinson's disease, plus carbidopa and entacapone. While carbidopa reduces the side effects of levodopa, entacapone optimizes its benefits, permitting Parkinson's disease patients to have an improved ability to perform everyday tasks and a reduction in symptoms associated with the disease.

Within one to two years, almost 50 percent of Parkinson's disease patients receiving levodopa therapy begin to notice that their levodopa lasts for shorter periods of time, a phenomenon known as "wearing off."<sup>1</sup> In about 15 to 20 percent of patients, "wearing off" becomes extreme and disabling. Eventually, the effect of a levodopa dose may decrease from eight hours when patients begin levodopa therapy to only one to two hours.

"Levodopa is recognized as the cornerstone of Parkinson's disease therapy, but its long-term use is limited by its reduced ability to fully control Parkinson's disease symptoms," said Warren Olanow, MD, professor and chairman, Department of Neurology, Mount Sinai School of Medicine in New York City. "By blocking the enzymatic breakdown of levodopa, Stalevo provides more levodopa to the brain for a longer period of time. Potential patient benefits include simpler, more convenient dosing and more "on" time, during which Parkinson's symptoms are well-controlled and daily activities are improved."

"We are proud to introduce a product like Stalevo which can enhance the daily lives of many people with Parkinson's disease," stated Paulo Costa, president and CEO, Novartis Pharmaceuticals Corporation. "As the fourth Parkinson's drug Novartis has introduced in the United States, Stalevo is a clear example of our company's ongoing commitment to the Parkinson's community."

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1. Parkinson Study Group. Pramipexole vs. levodopa as initial treatment for Parkinson disease. A randomized controlled trial. JAMA 2000;284:1931-1938.

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The effectiveness of levodopa administered with carbidopa and entacapone in the treatment of Parkinson's disease was established in three 24-week multicenter, randomized, double blind placebo-controlled trials in patients with Parkinson's disease experiencing "wearing off". In these trials, patients benefited from increased "on" time, reduced "off" time, improved motor function and daily activities such as patients' ability to walk, dress, and maintain hygiene. The most common side effects of Stalevo therapy are dopaminergic in nature (e.g. dyskinesia, nausea). These side effects may be manageable with alteration in the drug dosing schedule. Other common side effects include diarrhoea, hyperkinesias, urine discoloration, hypokinesia, abdominal pain, dizziness, constipation, fatigue, pain and hallucinations.

#### **About Parkinson's disease**

Parkinson's disease, a chronic and progressive neurological condition, affects more than 1% of people over 65 years old. While its cause is unknown, the symptoms of Parkinson's disease are primarily the result of degeneration of dopaminergic cells, or neurons, in the *substantia nigra*, a part of the brain that controls and modulates movement. Symptoms include limbs that tremble; slowness of movement; stiffness and rigidity of limbs and gait or balance problems. As the disease progresses, these symptoms usually increase and impact a person's ability to work and function.

Stalevo will be marketed in the United States by Novartis Pharmaceuticals Corporation and manufactured by Orion Pharma.

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 "can expect", or similar expressions, or by express or implied discussions regarding potential future sales of Stalevo. Such statements reflect the current views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Stalevo will reach any particular sales levels. In particular, management's expectations could be affected by, among other things, 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 described herein as anticipated, believed, estimated or expected.

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**Investor Relations Release****EMEA updates Zometa® label to include longer-term efficacy data on prevention of bone complications in advanced cancers**

*Breast cancer patients have additional 20% reduced risk of bone complications with Zometa compared to pamidronate*

*Long term safety and efficacy of Zometa confirmed by these data*

Basel, 12 June 2003 Novartis announced today that it has received approval from the European Agency for the Evaluation of Medicinal Products (EMA) to expand the current marketing authorization for Zometa® (zoledronic acid) to include data on long-term treatment for patients with advanced cancers that have spread to the bone.

Novartis submitted the marketing authorization application for the updated labeling to the EMA in October 2002 and received a positive opinion from the Committee for Proprietary Medicinal Products (CPMP) in February 2003. The data upon which the application was based confirm the long-term (approximately two years) benefits of Zometa including a decrease in number of patients experiencing bone complications, delay in initial onset of bone complications and reduced risk of developing complications. Bone complications, also known as skeletal related events (SREs), include, among others, pathological fractures, a need for radiation or surgery to bone, spinal cord compression, and hypercalcemia.

This Phase III long term data, recently presented at the American Society of Clinical Oncology (ASCO) meeting, show treatment with Zometa significantly reduced the risk of developing bone complications in patients with breast cancer, multiple myeloma, prostate cancer, lung cancer and other solid tumor types, according to a prospective multiple event analysis. This prospective multiple event analysis demonstrated that breast cancer patients treated with Zometa 4 mg in a 15-minute infusion have a 20% lower risk of developing bone complications compared with those treated with pamidronate 90 mg in a two-hour infusion. Multiple event analysis is a rigorous and sensitive measure of the risk of developing the first as well as subsequent bone complications over the entire course of treatment.

Zometa is the first bisphosphonate to demonstrate efficacy in treating bone complications across a broad range of tumor types such as breast, prostate, renal cell and lung cancers, as well as multiple myeloma. Zometa was granted marketing authorization by the EMA in July 2002 for the prevention of bone complications in patients with advanced malignancies involving bone. This indication was based on data from three large pivotal trials of more than 3,000 patients that evaluated the drug for a treatment period of approximately one year.

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**Contraindications and adverse events**

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

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

The foregoing release contains forward-looking statements that can be identified by terminology such as "longer-term," "long-term" or similar expressions, or by express or implied discussions regarding potential future sales of Zometa. Such forward-looking statements reflect the current views of the company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Zometa to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee regarding future sales of Zometa. In particular, management's expectations regarding Zometa could be affected by, among other things, additional analysis of Zometa clinical data; new clinical data; unexpected clinical trial results; unexpected

regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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.

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#### Investor Relations Release

#### US International Trade Commission determines legal dispute between GSK and Novartis should go to trial

Basel, 11 June 2003 The US International Trade Commission (ITC) has decided that the legal dispute in the US between GlaxoSmithKline (GSK) and Novartis concerning the strain used to manufacture the antibiotic AmoxC (amoxicillin/clavulanic acid) should go to trial. Previously, on 9 April 2003, an ITC Administrative Law Judge had ruled against further proceedings and dismissed claims against certain Novartis Group companies on the basis that the strain lost any trade secrecy protection that it may have had when GSK entered into a prior settlement agreement with Novartis' subsidiary Biochemie. However, the ITC remanded the decision for further proceedings on the grounds that there are issues of fact that must be determined at trial.

Christian Seiwald, worldwide Head of Novartis' Generics Business Unit commented: "It is our firm conviction that we have acted correctly and ethically throughout and remain committed to ensuring that our high quality generic alternative continues to be available to prescribers and their patients in the US."

This release contains certain "forward-looking statements," relating to the Group's business, which can be identified by express or implied statements regarding the likelihood of the Novartis Group companies' final success in its litigation with GSK, and regarding its future ability to sell AmoxC in the US. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. Such risks include the risk that the Administrative Law Judge will rule against the Novartis Group companies at trial, or that the ITC or an appellate court may rule against the Novartis Group companies in a subsequent appeal, the risks of collateral litigation, market place risks that could adversely affect Geneva Pharmaceutical's ability to market AmoxC in the US as well as the other factors discussed in Novartis AG's Form 20-F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Elidel® cream provides fast relief for infants with atopic dermatitis**

*New study shows benefits of non-steroid Elidel cream 1% in less than three days*

Basel, 10 June 2003 Infants with atopic dermatitis may feel the benefit of Elidel® (pimecrolimus) Cream as quickly as 48 hours after the first application. Results of a large study of patients of 3-23 months with mild to very severe atopic dermatitis (eczema) show fast relief of symptoms, such as itching and disturbed sleep, for the infants and improved quality of life for the parents.

**Within 2-3 days of treatment, infants experienced less itching and slept better**

Already after two days of treatment, significantly more patients could be classified as "responders" with at least a 50% reduction of their itching with Elidel (27.3%) compared to the control group treated with vehicle (12.1%) (p=0.018). After 72 hours of treatment, the responder criterion was achieved by 46.1% in the Elidel group compared to 10.6% in the control group (p<0.001). Also on day 3, a ≥50% improvement in sleep loss was reported by 49.2% in the Elidel group and 25.8% in the control group (p= 0.002).

More than two thirds of the infants in the Elidel group achieved a ≥50% improvement in itching and sleep loss compared to the control group (p=0.001) after four weeks of treatment. Pruritus and sleep loss were assessed using a Visual Analog Scale ranging from 0-10 by the primary caregiver.

**Body area affected by disease and eczema severity decreased significantly after 3 days**

Three days after starting treatment, Eczema Area and Severity Index (EASI) scores fell by 38.5% from an average of 17.7 to 10.8 in infants treated with Elidel Cream compared to a small increase of 1.8 in those who used the control. At the end of the four week study, the EASI score had fallen to 5.5 in the Elidel group (69% reduction) compared to a rise of 0.9 in the control group.

"We knew that pimecrolimus was safe and effective at relieving atopic dermatitis in children and adults of all ages, but this study has shown just how quickly our youngest patients can start to feel the benefit," commented Professor Roland Kaufmann, from the Dermatological Clinic of the Johann Wolfgang Goethe University, Frankfurt in Germany.

**Treatment with Elidel improved parents' quality of life**

In addition to measuring atopic dermatitis scores, the new study also assessed the impact of treatment on the quality of life of the infants' parents, according to a five domain, 26 item questionnaire. At the end of the four-week study, statistically significant improvements (p<0.05) were seen in all five domains in parents of infants treated with Elidel: psychosomatic well being, social life, confidence in medical treatment, emotional coping and acceptance of disease.

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Professor Ulrich Wahn, Director of the Department of Pediatric Pneumology and Immunology of the Charité Clinic, Berlin, Germany, underlined that sleep loss due to night-time itching associated with atopic dermatitis can have a considerable impact on quality of life for both children and parents. "Within a short time of their infants starting Elidel, parents were reporting significant improvements in the social and emotional aspects of their everyday lives, suggesting that they were having fewer disturbed nights and less distress arising from their children's symptoms," he said.

At the end of the four-week, double-blind phase of the trial, infants from the control group were transferred to Elidel during a 12-week open label phase. During this time, their EASI scores also fell by 12 from 17.5 to 5.5 (69% reduction). During a further four-week follow up, during which no treatment was given, there was no indication of rebound symptoms. Elidel was well tolerated throughout the study, with adverse events suspected to be related to study medication reported in 3.8% of those using Elidel cream compared with 4.5% in the control group.

### About Elidel

Elidel Cream is a new non-steroid selective inhibitor of inflammatory cytokines which is licensed for the treatment of atopic dermatitis. Discovered by the Novartis Research Institute in Vienna, Austria, Elidel contains the active ingredient pimecrolimus, which is derived from ascomycin, a natural substance produced by the bacterium *Streptomyces hygroscopicus* var. *ascomyceticus*. Pimecrolimus selectively blocks the production and release of inflammatory cytokines from T-cells in the skin. It is these cytokines which trigger processes leading to the inflammation, redness and itching associated with eczema. Elidel is the first and only non-steroid prescription medication proven to help prevent disease flares in infants with atopic dermatitis when used at the first signs and symptoms<sup>1</sup>.

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 "may feel", "can start", "suggesting", or similar expressions, or by express or implied discussions regarding potential future sales of Elidel or potential new indications for Elidel. Such statements reflect the current views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Elidel will reach any particular sales levels, or that Elidel will be approved for any new indications in any market. In particular, management's expectations could be affected by, among other things, 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 described herein as anticipated, believed, estimated or expected.

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1. Kapp A, Papp K, Bingham A et al. Long-term management of atopic dermatitis in infants with topical pimecrolimus, a non-steroid anti-inflammatory drug. *J Allergy Clin Immunol* 2002; 110: 277-284.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**First and largest statin trial in renal transplant patients demonstrates that Lescol® reduces cardiac death and heart attack**

*ALERT results presented at American Transplant Congress and published on-line in The Lancet*

Basel, 3 June 2003 Lescol® (fluvastatin sodium) significantly reduces the combined incidence of cardiac death or non-fatal myocardial infarction (MI) in renal transplant patients compared to placebo, according to results of the Assessment of Lescol in Renal Transplantation (ALERT) study published today in the online version of *The Lancet* and being presented today at the American Transplant Congress, the joint annual meeting of the American Society of Transplant Surgeons and the American Society of Transplantation.

ALERT is a unique trial, representing the largest prospective study in renal transplant recipients and the first to study cardiac and renal outcomes in this population. The primary endpoint was defined as the occurrence of major adverse cardiac events (MACE), consisting of cardiac death, non-fatal MI or coronary intervention. Although not statistically significant, fluvastatin demonstrated a positive trend versus placebo on the primary endpoint of MACE. However importantly, the risk of cardiac death and non-fatal MI was significantly reduced in fluvastatin-treated patients compared to placebo. Cardiovascular disease accounts for up to 70% of deaths in patients with successful kidney transplants.

"The results of the ALERT study confirm the benefits of Lescol in the prevention of cardiac events in a challenging, high-risk patient population," said Joerg Reinhardt, Ph.D., Head of Pharma Development, Novartis Pharma AG. "It also confirms the proven safety of this statin medication, even in renal transplant patients, who are not only at high risk for a cardiovascular disease but also have an increased risk of drug interactions."

ALERT was a multicenter, placebo-controlled study, enrolling 2,102 patients from nine countries, examining the effect of Lescol 40-80 mg daily versus placebo in renal transplant recipients receiving immunosuppressive therapy with cyclosporin who had mild to moderate elevated LDL cholesterol levels. Follow-up extended for five to six years.

**Key Findings**

Treatment with Lescol demonstrated a favorable trend towards reduction in the risk of MACE, the primary endpoint for this trial, although the difference compared to placebo was not statistically significant ( $p=0.139$ ). On the hard cardiovascular endpoints, treatment with Lescol (40-80 mg daily) demonstrated a significant 38% reduction in the risk of cardiac death ( $p=0.031$ ), a 32% reduction in the risk of non-fatal MI ( $p=0.050$ ) and a 35% reduction in the cumulative incidence of cardiac death or first non-fatal MI ( $p=0.005$ ).

Fluvastatin significantly reduced low-density lipoprotein cholesterol (LDL) by 32% compared with placebo and brought most patients to LDL target based on US and European guidelines for heart disease prevention. ALERT also found that treatment with fluvastatin lowered triglyceride levels compared with placebo. Levels of high-density lipoprotein (HDL) cholesterol were significantly increased by 7 to 13% during the first four years of the study although the difference compared to the placebo group became negligible at study end for certain factors, which are currently being investigated.

In ALERT, no differences were seen in adverse event rates between the two groups. Similar incidences of critical elevations of alanine aminotransferase (ALT) or creatine kinase (CK) levels occurred in the Lescol- and placebo-treated populations. These data underscore the excellent safety profile of Lescol and are consistent with pooled analyses from previous clinical trials with Lescol and Lescol XL, which found that the rates of CK elevation with Lescol, alone or in combination with fibrates, were similar to placebo.

**About Lescol/Lescol XL**

Lescol and Lescol XL are statin drugs used in the treatment of cholesterol, atherosclerosis and vascular disease. Novartis introduced Lescol extended-release, once-daily 80 mg formulation in 2000 (Lescol XL), which has been shown in trials to provide effective lipid management, with reductions in harmful LDL-cholesterol of 38%, in triglycerides of 31% and increases in favourable HDL-cholesterol of up to 21%.<sup>1</sup>

This press release contains forward-looking statements relating to the business of Novartis, which can be identified by express or implied discussions regarding potential new indications or future sales for Lescol or Lescol XL. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantees that the aforementioned clinical trial will result in any new indications for Lescol or Lescol XL in any market. Nor can there be any guarantees regarding any future sales of Lescol or Lescol XL. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results,

performances or achievements that may be expressed or implied by such forward-looking statements. These factors include, among other things, uncertainties relating to clinical trials and product development, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection, and competition in general, increased government pricing pressures, as well as factors discussed in the Company's Form 20F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated, or expected.

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Transplanted kidneys from living donors survive longer using immunosuppression with Neoral® compared with tacrolimus**

*Major new study of over 7,000 living donor kidney transplant patients finds type of immunosuppressive therapy makes a difference to long-term outcome*

Basel, 3 June 2003 The long-term chances of survival of a transplanted kidney from a living donor are significantly greater with immunosuppressive therapy based on Neoral® (cyclosporin microemulsion) than with therapy based on tacrolimus, according to a major new study presented today at this year's American Transplant Congress in Washington, DC, USA.<sup>1</sup> Immunosuppressive therapy is used to help prevent the body from rejecting a transplanted organ.

Over 40% of all new kidney transplant patients in the USA receive an organ from a living donor.<sup>2</sup> The retrospective study assessed data from over 7,000 living donor kidney transplant recipients registered within the US organ transplant registry United Network for Organ Sharing (UNOS) and aimed to compare organ survival over three years in patients receiving one of the two most commonly used immunosuppressive regimens: Neoral or tacrolimus, both in combination with mycophenolate mofetil and steroids.

The study concluded that three-year graft (organ) survival rates for the transplanted kidney were significantly higher in patients who received Neoral compared to patients who received tacrolimus. Specifically, the results showed that:

patients who received tacrolimus had a 28% higher risk of losing their transplanted organ or of dying (all cause graft failure) than patients who received Neoral (hazard ratio of 1.28). When patients who died with a functioning organ were excluded from the analysis of organ failures, patients treated with tacrolimus had a 25% higher risk of losing their organ (hazard ratio of 1.25).

transplanted kidneys in patients who were taking Neoral were expected to survive for four years longer on average than in patients taking tacrolimus, according to the results of another prognostic tool, the "estimated graft half-life" (20.8 years graft half-life survival time for the Neoral group vs 16.1 years for the tacrolimus group, all cause graft failure).

Lead investigator Dr Steven Takemoto, of the UCLA School of Medicine, Los Angeles, commented: "Outcomes data are an accurate reflection of how different therapies perform in the real world. It is important to know the longer-term effect of different immunosuppressive treatments on survival of transplanted organs. Analysis of data from transplant registries provides an opportunity to examine outcomes from many thousands of patients over an extended time period, provided the data are statistically adjusted to match the two groups as closely as possible in terms of other criteria, such as patient and donor age, race, sex and genetic compatibility. Using this approach, our study indicated a clear advantage for Neoral versus the main alternative, tacrolimus, in prolonging the survival of transplanted kidneys from living donors."

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Anne Frankton, a transplant coordinator at Nottingham City Hospital, UK, commented: "Living donor transplantation is a huge emotional and physical investment for both the patient and donor. The loss of a transplanted kidney is a devastating event under any circumstances but is particularly traumatic in the case of living donors who have donated one of their kidneys to help a loved one and endured major surgery in the process. For the person losing the transplant it means a return to the ordeal of regular dialysis, involving hours hooked up to a blood-cleaning machine three times a week and the consequent impairment of their independence and quality of life. It is therefore vital that studies like this are undertaken to help doctors find ways to reduce the risk of transplant failure."

Approximately 30,000 people in Europe and the US receive kidney transplants each year, a significant number of these are from living donors.<sup>2</sup> Immunosuppressive treatment is vital to prevent the body rejecting the new organ. Neoral is the main component of current immunosuppressive treatment strategies in transplant patients and remains the most commonly prescribed immunosuppressant worldwide.

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 "long-term", "expected to", "estimates", or similar expressions, or by express or implied discussions regarding potential future sales of Neoral. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There can be no guarantees that Neoral will reach any particular sales levels. Any results expressed or implied by such forward-looking statements can be affected by, among other things, uncertainties relating to product development and clinical trials, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20-F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

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#### NOTES TO EDITORS:

Graft half-life is an estimate of the length of time for half of the patients in a study to lose their transplanted organ. This measurement, based on rates of loss in years two to three, estimates long-term differences in organ survival times between the two treatment groups.

**For an electronic and downloadable version of this press release**, please visit the transplantation media resource site [www.transplantsquare.com](http://www.transplantsquare.com).

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Giving the right nutrients before surgery cuts postoperative infections and lowers hospital costs**

Basel, June 3, 2003 Preoperative administration of an oral supplement containing immune-enhancing nutrients gives a boost to patients' immune system that helps them to fight off postoperative infections so they spend less time in hospital.

New data presented at the recent 16<sup>th</sup> annual meeting of the Surgical Infection Society Europe (29<sup>th</sup>-31<sup>st</sup> May 2003) in Cernobbio, Italy, Dr Luca Gianotti from the Department of Surgery at the University of Milano-Bicocca, Monza, Italy, showed that major operations for cancer of the gastrointestinal tract are still associated with a high risk of complications and a high consumption of health care resources.

Surgical trauma increases levels of proinflammatory cytokines and lowers host defense mechanisms. But administration of oral IMPACT® an enteral immune-enhancing drink, (supplemented with arginine, n-3 polyunsaturated fatty acids and ribonucleotides) is able to modulate the immune and inflammatory responses altered by surgical trauma, upregulating gut microperfusion and oxygen metabolism.[1]

Randomized trials have shown that preoperatively loading elective surgery patients with immune-enhancing substrates in an oral formula for 5 days and continuing therapy by jejunal infusion for 7 days after surgery results in significant reductions in postoperative infections and length of hospital stay in patients undergoing gastrointestinal surgery for cancer,[2] with a subsequent significant reduction of health care costs.[3]

Post-hoc analysis of these data suggested that even patients who were unable to comply with postoperative immunonutrition benefited from a reduction in complications. So to determine whether preoperative treatment was as effective as perioperative treatment in reducing postoperative complications, Dr Gianotti conducted two trials in patients with gastrointestinal cancer comparing both approaches with control group who received no additional immune-enhancing supplementation to normal diet. One trial enrolled malnourished patients (n=150)[4] the other enrolled well-nourished patients (n=305).[5]

The published results showed that in malnourished patients (those who had lost more than 10% of body weight in the previous 6 months) patients in the control group had significantly more postoperative complications than those treated preoperatively, while those treated before and after surgery even fewer. This was reflected in patients' total length of hospital stay, which was significantly shorter in the preoperative (13.2 days) and perioperative (12.0 days) groups than in the control group (15.3 days).

But in well-nourished patients, oral preoperative supplementation showed similar results to perioperative immune-enhancing supplementation, and both were superior to the control approach:

Incidence of postoperative infections was 14% in the preoperative group and 16% in the perioperative group, but over 30% in the control group (P=0.006 vs. preoperative; P=0.02 vs. perioperative).

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Length of hospital stay was 11.6 days in the preoperative group, 12.2 days in the perioperative group, and 14.0 days in the control group (P=0.008 vs. preoperative and P=0.03 vs. perioperative).

Dr Gianotti explained: "Preoperative feeding 5 days prior to surgery modulates the host immune defense mechanisms sufficiently to avoid surgical depression of the immune system, and thus to fight off postoperative infections."

"Whether patients are malnourished or well-nourished, preoperative supplementation with an immune-enhancing formula will ensure that patients are fit for surgery," he said. "But in well-nourished patients we can avoid possible side-effects of enteral feeding, such as nasojejunal tube clogging or removal, abdominal cramps and save the costs of providing postoperative immunonutrition."

But the real cost savings from this preoperative immune-enhancing supplementation strategy emerged when he added up the costs of managing postoperative complications (obtained from the Italian Ministry of Health) in this trial.

Unsurprisingly, for patients with no complications the cost was lowest in the control group, but for patients with complications the cost per patient was lowest in the preoperative treatment group.

Adding together the costs of nutrition plus the costs of managing both complicated and uncomplicated patients), Dr Gianotti found the total costs as:

723,368 Euro for control group

681,496 Euro for perioperative treatment

578,085 Euro for preoperative treatment.

By relating these costs to Diagnosis-Related-Group (DRG) reimbursement rates for the same patients, Dr Gianotti found that costs in the control group accounted for 93% reimbursement of DRG reimbursement while they accounted for just 78% in the preoperative and 86% in the perioperative group, suggesting that hospitals could save money by adopting preoperative immunonutrition.

"The major cost of surgical complications, particularly infectious complications, is the cost of prolonged hospital stays," said Dr Gianotti. "The benefit of immunonutrition is mainly in reducing the rate of infectious complications. The cost of providing preoperative immune-enhancing diet was more than offset by the reduced length of stay from this approach."

He urged surgeons to adopt a strategy of "supporting malnourished patients with a perioperative immune-enhancing supplementation to normal diet and to support well nourished patients with the preoperative approach without postoperative prolongation."

Novartis Medical Nutrition 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.

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**MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG**

**Early data from 6 600 patients in Glivec® Expanded Access Program consistent with published survival data for Ph+ chronic myeloid leukemia patient**

*Expanded Access Program provides new model for bringing innovative cancer therapies to patients*

Basel, 2 June 2003 Early data from more than 6 600 patients in a global program that provided patients with early access to Glivec® (imatinib)\*, prior to its regulatory approval, are consistent with published results on survival from the Phase II clinical trials in patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.

Novartis established the Expanded Access Program (EAP) in April 2000 to provide early access to Glivec in response to the extraordinary patient demand for the drug that resulted from unprecedented response rates reported in the Phase I Ph+ CML clinical trials. The EAP provided the drug at no cost to patients in 37 countries prior to the drug's approval. The data presented at the meeting of the American Society of Clinical Oncology (ASCO) this week in Chicago, Illinois, were collected from EAP participants, and were not needed for marketing authorization. They are consistent with previous findings on time to progression, overall survival and safety data.

"We feel gratified that our efforts to speed access to Glivec for patients with limited treatment options have helped so many people," said David Epstein, President, Novartis Oncology.

**EAP Results**

In the EAP, patients in the blast crisis (BC) and accelerated phases (AP), received 600mg Glivec daily, while those in chronic phase (CP) who had failed treatment with interferon-alpha, received 400mg daily. The results collected from 6 617 EAP patients and 1 027 patients in the



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Phase II trials, in all three of these phases of Ph+ CML, were as follows:

	EAP			Phase II		
	BC N=784	AP N=2201	CP N=3632	BC N=260	AP N=235	CP N=532
Time to Progression (TTP) % at 12 months	18	73	94	19	68	92
Overall Survival (OS) % at 12 months	33	85	97	31	80	98

In addition, discontinuation rates of less than 6% were consistent with the previously reported tolerability profile. An additional 595 patients in the EAP had cancers other than Ph+ CML and are not included in this comparison.

Recognizing the need to continue helping patients gain access to Glivec even after its approval, Novartis established the Glivec International Patient Assistance Program (GIPAP). The program provides Glivec free of charge to eligible patients, according to each country's approved registration, who are not insured or reimbursed and have no other financial recourse. Since its inception, GIPAP has provided Glivec to more than 1 500 patients in 34 countries. A similar program, PAP (Patient Assistance Program), is offered in the US.

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### About Glivec

Glivec is indicated for the treatment of newly diagnosed adult and pediatric patients with Ph+ CML in the EU, Switzerland, and a number of other markets. Glivec is approved in the US for newly diagnosed adult patients with Ph+ chronic phase CML and pediatric patients with Ph+ chronic phase CML whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy. In addition, Glivec is already approved in over 80 countries for the treatment of adult patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.

Glivec is also approved in the EU, US and more than 45 other countries for the treatment of patients with Kit (CD 117)-positive unresectable and/or metastatic malignant gastrointestinal stromal tumours (GISTs).

### Contraindications, Warnings and Adverse Events

In the first-line study (IRIS), the safety profile with Glivec was similar to that of previous Phase II studies in other CML patients. The majority of patients treated with Glivec experienced adverse events at some time. Most events were of mild to moderate grade and treatment was discontinued for adverse events only in 2% of patients in chronic phase, 3% in accelerated phase and 5% in blast crisis. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, as well as neutropenia and thrombocytopenia.

The most common undesirable effects experienced during Glivec treatment in GIST are: headache, nausea, vomiting, diarrhea, dyspepsia, myalgia, muscle spasm and cramps, joint swelling, dermatitis, eczema, rash, edema, fluid retention, neutropenia, thrombocytopenia or anemia.

Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

The foregoing release contains forward-looking statements that can be identified by terminology such as "early data", or similar expressions, or by express or implied discussions regarding potential future revenue from Glivec, or regarding the long-term impact of a patient's use of Glivec. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Glivec will achieve any particular revenue levels in the future. Neither can there be any guarantee regarding the long-term impact of a patient's use of Glivec. In particular, management's expectations regarding Glivec could be affected by, among other things, additional analysis of Glivec clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to 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.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Study shows longer pre-operative treatment with Femara® significantly increases chance of breast-conserving surgery in post-menopausal women with locally advanced breast cancer**

*Results reported at annual meeting of American Society of Clinical Oncology: 67% of patients eligible for breast-conserving surgery*

Basel, 2 June 2003 Extended pre-operative treatment with Femara® (letrozole tablets) of post-menopausal women with locally advanced primary breast cancer was found to further reduce the size of tumors than a shorter 4-month course of Femara, according to data presented today at the annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Illinois, USA.

**Study Details**

The data demonstrated that Femara is highly effective primary systemic (pre-operative) treatment when taken for 4-to-8 months prior to surgery. In this trial, treatment resulted in a mean reduction in tumor size of 68%, which ultimately allowed 67% of patients to undergo breast-conserving surgery (BCS) during the timeframe evaluated. In addition to the significant reduction in mean tumor size, 6% of patients experienced a complete response; 64% had a partial response; and 13% had a minor response. In those women that had responded within the first 4 months, longer treatment led to a further reduction in tumor size. Based on these findings, the authors state that with additional research, prolonging pre-operative treatment with Femara could become an important therapeutic option.

The open clinical trial included 33 postmenopausal patients from six centers in Germany. At the start of the study, all participants had primary invasive ER/PgR positive breast cancer, and tumors that were deemed ineligible for BCS due to their size. Participants received Femara 2.5 mg daily for a minimum of four months and a maximum of eight months prior to surgery. Tumor assessment was performed monthly by clinical examination, mammography and ultrasound. The study was initiated after a larger, multinational trial in 324 patients had previously reported that after four months of treatment, 45% of patients on Femara were candidates for BCS, compared with 35% of those taking tamoxifen (P=0.022).

**About Femara**

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

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## Femara Contraindications and Adverse Events

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

The foregoing release contains forward-looking statements that can be identified by terminology such as "chance," "could become," 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.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

### **Novartis Medical Nutrition acquires Semper Clinical Nutrition, a leader in medical nutrition in the Nordic region**

Stockholm, June 2, 2003 Novartis Medical Nutrition, headquartered in Nyon, Switzerland, today announced the acquisition of Semper Clinical Nutrition, the second largest medical nutrition business in the Nordic region. Semper Clinical Nutrition is part of Semper AB, a subsidiary of Arla Foods amba, headquartered in Viby, Denmark. The acquisition follows the success of a strategic alliance established in 2001 between Novartis Medical Nutrition and Semper Clinical Nutrition in Finland and Denmark. Financial terms of the transaction are not disclosed. The acquisition is expected to close within 1-2 months.

Michel Gardet, Global Head of Novartis Medical Nutrition, said, "This acquisition provides an excellent growth platform. It compliments our current product portfolio in the Nordic region and also gives us the potential to further leverage our disease specific product capabilities in Scandinavia. I am particularly pleased about the quality of Semper Clinical Nutrition's dedicated sales force. We expect a fast and smooth integration process, so that Nordic customers can benefit from an expanded range of products and services from one supplier as soon as possible."

With its staff of 26 associates, Semper Clinical Nutrition generated sales of SEK 100 million (approximately USD 10 million) in fiscal year 2002. Under the Semper umbrella brand the company sells a portfolio of strong products and brands such as Komplet N ring®, Addera®,

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Acceptera®, Resorb® and Afi Nutrin® in the nursing home, hospital and pharmacy channels. Semper Clinical Nutrition is present in Sweden, Finland, Denmark, Norway and Iceland. The product range includes brands developed to meet the needs of people with specific diseases so called 'disease specific' nutritional products which are growing strongly.

Novartis Medical Nutrition, with global sales of USD 715 million in 2002, 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®.

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### 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 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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### 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: July 1, 2003

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: *Head Group Financial Reporting and Accounting*

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ENCLOSURES

Novartis Ophthalmics and Genentech announce development and commercialization agreement for age-related macular degeneration treatment, Lucentis

Results of LIS2T study indicate that Neoral® is associated with less diabetes and diarrhoea than tacrolimus in liver transplantation

FDA approves Xolair®, biotechnology breakthrough for asthma

New data confirm that Prexige® (lumiracoxib) is effective in relieving symptoms of osteoarthritis

NICE issues preliminary recommendation for Glivec® in England and Wales as first-line drug therapy for patients with chronic myeloid leukemia

Recipients of the 5<sup>th</sup> Annual Novartis Award in Diabetes honored today

FDA approves Stalevo for treatment of Parkinson's disease

EMA updates Zometa® label to include longer-term efficacy data on prevention of bone complications in advanced cancers

US International Trade Commission determines legal dispute between GSK and Novartis should go to trial

Elidel® cream provides fast relief for infants with atopic dermatitis

First and largest statin trial in renal transplant patients demonstrates that Lescol® reduces cardiac death and heart attack

Transplanted kidneys from living donors survive longer using immunosuppression with Neoral® compared with tacrolimus

Giving the right nutrients before surgery cuts postoperative infections and lowers hospital costs

Early data from 6 600 patients in Glivec® Expanded Access Program consistent with published survival data for Ph+ chronic myeloid leukemia patient

Study shows longer pre-operative treatment with Femara® significantly increases chance of breast-conserving surgery in post-menopausal women with locally advanced breast cancer

Novartis Medical Nutrition acquires Semper Clinical Nutrition, a leader in medical nutrition in the Nordic region

SIGNATURES